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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

RICHARD W MURRY

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Vol. 23, No. 19
May 20, 1994

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NOTICES OF AVAILABILITY (RFPs AND RFAs)

MOLECULAR AND STRUCTURAL APPROACHES TO ANTIVIRAL DRUG DESIGN

NIH GUIDE, Volume 23, Number 19, May 20, 1994

RFA AVAILABLE: AI-94-017

P.T. 34; K.W. 0740012, 1002019, 1002008, 0755025

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: June 22, 1994

Application Receipt Date: August 10, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

Therapeutic and prophylactic agents (other than vaccines) for viral infections that specifically inhibit virus replicative functions without interfering with those of the host cell processes are likely to provide clinical benefit with minimal toxicity. The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for research that applies an understanding of the genetics, structural biology, and molecular biology of virus replication and pathogenesis to the development of antiviral agents that are targeted to virus-specific or virus-induced functions. Research on any virus that is a human pathogen or that serves as a model for a human pathogen, except for human immunodeficiency virus (HIV) and/or other retroviruses, is an appropriate subject for an application.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Molecular and Structural Approaches to Antiviral Drug Design, is related to the priority area of therapy for viral diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The administrative and funding mechanism to be used to undertake this program will be the Cooperative Agreement (U01). Details of the responsibilities, relationships, and governance of a study funded under a cooperative agreement are discussed in the RFA under the section Terms and Conditions of Award.

The total project period for applications submitted in response to this RFA may not exceed five years. Awards and level of support depend on receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NIAID, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

This is a one-time RFA. At this time there are no plans to recompetitively this RFA. If the NIAID does not continue the program, awardees may submit grant applications through the usual investigator-initiated grants program.

FUNDS AVAILABLE

The estimated total funds (direct and indirect costs) available for the first year of support for awards under this RFA will be \$2,600,000. In Fiscal Year 1995, the NIAID plans to make nine to twelve awards. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit.

RESEARCH OBJECTIVES

The purpose of this RFA is to stimulate research in the development of novel molecularly targeted approaches to antiviral therapy. This includes strategies for both the design of novel specific agents and development of methods for selective drug delivery. The strategies proposed should involve a molecular rationale for anticipated antiviral activity without significant concomitant cellular and/or organism toxicity. These include, but are not limited to, the use of three dimensional structural knowledge for inhibitor design, receptor interference, substrate analogues for viral enzymes, antisense and ribozyme oligonucleotides, immune-based approaches such as bifunctional antibodies and T-cell reconstitution, peptides, peptidomimetics and rationally-based drug combinations. Targeted approaches to drug delivery are also encouraged since drug toxicity often results from effects on uninfected tissues. Collaborations between different scientific disciplines, such as chemistry and virology, as well as collaborations between industrial and academic investigators are encouraged. Virus systems may be any (except HIV and related lentiviruses) that provide a model for a clinically important human viral infection. Possible choices include, but are not limited to, hepatitis B, C, and D virus, papillomavirus, cytomegalovirus, herpes simplex virus, varicella zoster virus, influenza viruses, respiratory syncytial virus, parainfluenza, coxsackievirus, dengue, arenaviruses, bunyaviruses, and rhinovirus.

It is possible that research applications will involve the use of clinical specimens. If so, the issues discussed below in the section STUDY POPULATIONS should be addressed regarding the populations from which the specimens are obtained. Applications to conduct clinical trials are not responsive to this RFA and will be returned to the applicant.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 22, 1994, a letter of intent that includes a descriptive title of the overall proposed research, the name, address and telephone number of the Principal Investigator, the number and title of this RFA, and a list of any other key investigators and their institution(s). The letter of intent is to be sent to Dr. Olivia Preble at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted on the standard research grant application form PHS 398 (rev. 9/91). For purposes of identification and processing, item 2a on the face page of the application must be marked "YES" and the RFA number and the words "MOLECULAR AND STRUCTURAL APPROACHES TO ANTIVIRAL DRUG DESIGN" must be typed in. The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review.

Application forms may be obtained from the institution's office of sponsored research or its equivalent and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. Applications must be received by August 10, 1994.

REVIEW CONSIDERATIONS

Applications will be reviewed by the Division of Research Grants (DRG) for completeness and by NIAID for responsiveness to this RFA. Incomplete and non-responsive applications will be returned to the applicant without further consideration. The NIAID will remove from further competition those applications judged to be noncompetitive for award and will notify the applicant. Those applications judged to be competitive for award will be further reviewed for scientific and technical merit by an appropriate review committee convened by the NIAID. A second level of review will be provided by the NIAID Advisory Council.

AWARD CRITERIA

Funding decisions will be made on the basis of scientific and technical merit as determined by peer review, program needs and balance, and the availability of funds.

INQUIRIES

Written and telephone inquiries, requests for the RFA, and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA and inquiries regarding programmatic issues to:

Catherine Laughlin, Ph.D.
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3A22
Bethesda, MD 20892
Telephone: (301) 496-8285
FAX: (301) 402-1456

Questions regarding review procedures may be addressed to:

Olivia Preble, Ph.D.
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C19
Bethesda, MD 20892
Telephone: (301) 496-8208
FAX: (301) 402-2638

Direct inquiries regarding fiscal matters to:

Ms. Barbara Huffman
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B26
Bethesda, MD 20892
Telephone: (301) 496-7075
FAX: (301) 480-3780

Schedule

Letter of Intent Receipt Date: June 22, 1994
Application Receipt Date: August 10, 1994
Scientific Review Date: November 1994
Advisory Council Date: February 1995
Earliest Award Date: July 1995

AUTHORITY AND REGULATIONS

This program is supported under authorization of the Public Health Service Act, Section 301 (c), Public Law 78-410, as amended. The Catalogue of Federal Domestic Assurance Citation is Sec. 93.856, Microbiology and Infectious Diseases Research. Awards will be administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

THE ROLE OF HELICOBACTER IN CANCER

NIH GUIDE, Volume 23, Number 19, May 20, 1994

RFA AVAILABLE: CA/DK-94-024

P.T. 34; K.W. 0715035, 0755030, 1002027

National Cancer Institute
National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: June 17, 1994
Application Receipt Date: August 11, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Cancer Institute (NCI) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invite investigator-initiated research grant applications to support basic studies on defining the role of the bacteria *Helicobacter* in human cancer.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, The Role of Helicobacter in Cancer, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Applications from minority and women investigators are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for each application submitted in response to this RFA may not exceed four years.

The anticipated Award date is April 1, 1995. Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of an award will vary also.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures.

FUNDS AVAILABLE

Approximately \$2,000,000 (\$1,500,000 from NCI and \$500,000 from NIDDK) in total costs per year for up to four years will be committed to fund applications which are submitted in response to this RFA. It is anticipated that eight to nine awards will be made.

RESEARCH OBJECTIVES

Epidemiologic studies have consistently demonstrated an association between Helicobacter pylori and gastric cancer. A recent study of over 3000 subjects from 13 countries showed a six-fold risk of gastric cancer in populations with H. pylori infection compared to populations with no infections. A longitudinal study of patients with gastric adenocarcinoma showed that H. pylori infection was a risk factor, and while the relationship between H. pylori and gastric lymphoma of mucosa-associated lymphoid tissue (MALT) was only suggestive at that time, H. pylori has subsequently been confirmed as a risk factor for gastric lymphoma. These population studies indicate that H. pylori infections acquired in childhood lead to chronic gastritis that persists for decades, and in susceptible people progresses to atrophic gastritis, intestinal metaplasia and dysplasia. In underdeveloped countries, up to 50 percent of children are infected by the age of 10 years, and while the childhood prevalence is lower for most populations, up to 50 percent of adults are infected by age 60. While there are socioeconomic, dietary and other cofactors involved in gastric cancer, the lack of a basic understanding of the oncogenic mechanism of H. pylori and its role as a factor or co-factor in gastric cancer limits our understanding of this disease.

On October 16, 1993, the Biological Carcinogenesis Branch, DCE, NCI sponsored a workshop entitled "Helicobacter and Cancer." Dr. Webster Cavenee, a member of the DCE Board of Scientific Counselors, chaired the workshop. The purpose of the workshop was to assess the current state of knowledge on the role of Helicobacter pylori in gastric cancer in humans. This RFA is issued in accordance with the workshop recommendations that extramural research be stimulated in this area with set-aside funds.

SPECIAL REQUIREMENTS

The principal investigator of an R01 application must spend a minimum of 20 percent time and effort on this project.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 17, 1994, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it is requested in order to provide an indication of the number and scope of applications to be reviewed. It also allows Institute staff to estimate the potential review workload and to avoid conflict of interest in the review. The letter of intent is to be sent to Dr. Thomas E. Nightingale at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248; and from the NCI Program Director listed under INQUIRIES.

Applications must be received by August 11, 1994. An application received after that date will be returned to the applicant. The Division of Research Grants (DRG) will not accept any application in response to this RFA that is the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the Institutes in accordance with the review criteria listed below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA. Applications judged to be competitive will be discussed and be assigned a priority score, and will also receive a second level of review by the appropriate ICD's National Advisory Council/Board. Applications determined to be non-competitive will be withdrawn from further consideration and the principal investigator/program director and the official signing for the applicant organization will be promptly notified.

The following review criteria will apply:

1. The scientific merit, technical and medical significance of the proposed research, including the appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research. Familiarity with the proposed techniques should be demonstrated, e.g., by the presentation of preliminary data.
2. The research experience, expertise and qualifications of the principal investigator and proposed staff and/or collaborators to perform the proposed experiments.
3. Documentation of the adequacy of the facilities and resources necessary to perform the research.

AWARD CRITERIA

The earliest anticipated date of award is April 1, 1995.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA, inquiries regarding fiscal matters, and address the letter of intent to:

Thomas E. Nightingale, Ph.D.
Division of Cancer Etiology
National Cancer Institute
Executive Plaza North, Room 540
Bethesda, MD 20892
Telephone: (301) 496-1951

Frank A. Hamilton, M.D., M.P.H.
Division of Digestive Diseases and Nutrition
National Institute of Diabetes and Digestive Disease and Kidney Diseases
Westwood Building, Room 3A15B
Bethesda, MD 20892
Telephone: (301) 594-7571

Direct inquiries regarding fiscal matters to:

Mr. Earl Bowman, Jr.
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800, Ext. 217

Mrs. Thelma Jones
Grants Management Branch
National Institute of Diabetes and Digestive Disease and Kidney Diseases
Westwood Building, Room 649
Bethesda, MD 20892
Telephone: (301) 594-7543

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.393, Cancer Cause and Prevention Research. Awards are made under the authorization of the Public Health Service (PHS) Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 U.S.C. 241 and 285) and administered under PHS and HHS grants policies and grant regulations and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

CANCER PREVENTION AND RURAL HEALTH

NIH GUIDE, Volume 23, Number 19, May 20, 1994

RFA AVAILABLE: CA-94-019

P.T. 34; K.W. 0715035, 0730075, 0745027, 0745020

National Cancer Institute

Letter of Intent Receipt Date: June 20, 1994

Application Receipt Date: August 19, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Public Health Applications Research Branch, Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites research grant applications for research projects to develop, implement, and evaluate cancer prevention and early detection intervention strategies for rural populations.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Cancer Prevention and Rural Health, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, public and private, for-profit and non-profit, organizations such as universities, public health departments, voluntary organizations, research centers, hospitals, consortia of health providers, and units of state and local governments serving a substantial rural population. Collaborating applicant organizations and/or institutions with multidisciplinary expertise and access to rural populations are encouraged. Awards will not be made to foreign institutions and applicants from domestic organizations may not include international components. Applications from minority and women investigators are encouraged.

MECHANISM OF SUPPORT

Support of this program will be through the NIH individual research grant (R01). Applicants will be responsible for the planning, direction, and execution of the proposed project. However, it is anticipated that grantees funded under this RFA, will meet regularly for purposes of sharing design and evaluation strategies, comparing results where possible, and distilling lessons learned from all grant projects (See SPECIAL REQUIREMENTS). The total project period for an application submitted in response to this RFA may not exceed four years. The anticipated award date is March 1, 1995.

This RFA is a one-time solicitation. Generally, future unsolicited competitive continuation applications will compete with all investigator-initiated applications and be reviewed by the Division of Research Grants (DRG). However, if the NCI determines that there is a sufficient continuing program need, a request for competitive continuation applications will be announced. Only recipients of awards under this RFA will be eligible to apply.

FUNDS AVAILABLE

Approximately \$1,000,000 in total costs per year for up to four years will be committed to specifically fund applications that are submitted in response to this RFA. It is anticipated that three to five awards will be made and that the average annual direct costs will be \$175,000 per award. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. The total project period for an application submitted in response to the present RFA may not exceed four years. The earliest feasible start-date for the initial awards will be March 1, 1994. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The NCI is interested in stimulating research to develop effective methods for increasing cancer prevention and early detection services in rural populations and settings. The primary goal of this project is to develop, implement, and evaluate cancer prevention and early detection intervention strategies for rural populations and settings.

Definition of Rural - For purposes of this procurement, rural refers to areas of low population size and density that are categorized as 1) nonmetropolitan, using the designation of Metropolitan Statistical Areas by the U.S. Office of Management and Budget (OMB) or 2) rural, using the definition formulated by the U.S. Bureau of the Census (RHRP 1991).

Intervention Approaches - Investigators are encouraged to submit applications that focus on the prevention and/or screening and early detection of cancer. Research projects should address the cancer concerns of special relevance to rural populations. Appropriate behavioral, educational and/or organizational scientific theories should provide the foundation for identification of barriers to cancer prevention and control in rural populations and settings, design of appropriate intervention approaches and evaluation of intervention outcomes. Interventions may be targeted to individuals within rural communities, health care providers serving rural communities, public health structures, community organizations, or other appropriate individuals and/or groups. Interventions may address individual, community

and/or organizational level barriers to effective cancer prevention and control. Consideration must be given to the specific demographic, socioeconomic, cultural, and geographic factors that affect rural health-related behaviors and health provider practices.

Evaluation - Evaluation of the effectiveness of interventions to improve the health status of rural residents is a critical component of this RFA. An adequate design must be employed to reliably demonstrate the effectiveness of interventions in reaching the target population and affecting cancer prevention and control practices. Randomization of the target population to intervention and nonintervention groups is the preferred study design, although other well justified study designs with appropriate comparisons, such as multiple time series designs, will be considered. Final outcome measures should reflect improvements in health status and/or health-related behaviors, and may include for example, changes in stage at diagnosis, proportion of unstaged cases at diagnosis, number of preventive care visits, number and frequency of screening tests performed, compliance with screening guidelines, case fatality, time from diagnosis to treatment. Interim measures such as improvements in knowledge, attitudes, beliefs and/or intentions may be included if relevant to the intervention being tested.

Applications must include a clear plan for process evaluation. Process evaluation should provide information about implementation of the intervention and factors that both positively and negatively influenced implementation and any changes to the intervention as it was being implemented. Process information should be used to facilitate intervention design and implementation as well as interpretation of outcome results.

High priority will be given to research projects that are applicable to rural communities nationwide and that can be easily replicated and disseminated. Successful interventions developed through this research will be used to assist health professionals working in rural areas around the country to address cancer prevention and early detection needs. Research results will be disseminated through appropriate NCI programs such as the Appalachia Leadership Initiative on Cancer (ALIC), the Cancer Information Service (CIS), the Cancer Centers, and the Community Clinical Oncology Programs (CCOPs).

SPECIAL REQUIREMENTS

Investigators will be expected to supply a final report in a specific format, which summarizes both successes and failures in order to contribute to the dissemination of community intervention research. In addition, grantees may be expected to participate in a joint summary of results of all grants.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 20, 1994, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which an application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the final review of subsequent applications, the information it contains is helpful in planning for the review of applications. It allows NCI staff to estimate the potential review workload and to avoid possible conflict of interest in review. The letter of intent is to be sent to Dr. Marianne Haenlein Alciati at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications must be received by August 19, 1994. If an application is received after that date, it will be returned. The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, Maryland 20892 (301-594-7248), and from the NCI Program Director listed under INQUIRIES.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) for completeness and for responsiveness by the NCI. Incomplete applications will be returned to the applicant without further consideration. If the applicant is not responsive to the RFA, NCI staff will contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next review cycle. Questions concerning the responsiveness of proposed research to the RFA are to be directed to the Program Director listed under INQUIRIES.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Marianne Haenlein Alciati, Ph.D.
Public Health Agency Section
National Cancer Institute
Executive Plaza North, Room 233
Bethesda, MD 20892
Telephone: (301) 496-8584

Direct inquiries regarding fiscal matters to:

Robert E. Hawkins
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 242
Bethesda, MD 20892-4200
Telephone: (301) 496-7800, ext. 213

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399, Cancer Control. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under HHS policies and grant regulations. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

RESEARCH IN INNOVATIVE STRATEGIES TO REDUCE TOBACCO USE

NIH GUIDE, Volume 21, Number 17, May 6, 1992

RFA AVAILABLE: CA-94-015

P.T. 34; K.W. 0404019, 0745027

National Cancer Institute

Letter of Intent Receipt Date: June 29, 1994
Application Receipt Date: September 22, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) invites research grant applications to study strategies to develop, implement, and disseminate effective tobacco control interventions. Tobacco control interventions are those interventions that can influence large populations to reduce tobacco use. These interventions include, but are not necessarily limited to, restrictions on the sale of tobacco to minors, restrictions on indoor smoking, increases in tobacco excise taxes, and restrictions on tobacco advertising. The goal of this research is to assist policy makers and public health professionals in the enactment and enforcement of effective tobacco control policy interventions.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Research in Innovative Strategies to Reduce Tobacco Use, is related to the priority area of tobacco. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private institutions, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research project grant (R01) mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA may not exceed four years. The anticipated award date is July 1, 1995. Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of an award will also vary. This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary NIH peer review procedures.

FUNDS AVAILABLE

Approximately \$4,000,000 in total costs for four years (\$1,000,000 per year for each of four years) will be committed specifically to fund applications submitted in response to this RFA. It is anticipated that three or more new awards will be made, dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

Legislation and other policy interventions can decrease tobacco use. Effective policy interventions include increases in tobacco excise taxes, restrictions on indoor smoking, restrictions on tobacco advertising and promotion, and restrictions on minors' access to tobacco products. There remain many questions about the most effective strategies

to develop, implement, enforce, and disseminate tobacco control policies. This program is intended to stimulate innovative behavioral, public health, and economic research on tobacco control policy interventions, including the analysis of their feasibility, effectiveness and consequences of implementation. The goal of this research is to assist policy makers and public health professionals in the enactment and enforcement of effective tobacco control policies.

SPECIAL REQUIREMENTS

It is expected that grantees will participate in a series of collaborative meetings at NCI. Although independence and originality are encouraged in the approaches of the various investigators, they are expected to share ideas, experiences, and information in attempting to reach their common goal. Funds should be budgeted to permit travel of senior staff to Bethesda, Maryland twice a year over the course of the grant.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 29, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NCI staff to estimate the potential review workload and to avoid conflict of interest in the review. The letter of intent is to be sent to Dr. Marc Manley at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248; and from the NIH program administrator listed under INQUIRIES. Applications must be received by September 22, 1994.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and for responsiveness by the NCI. Incomplete applications will be returned to the applicant without further consideration. Those applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the Division of Extramural Activities, NCI. The second level of review will be provided by the National Cancer Advisory Board. Review criteria are provided in the RFA.

AWARD CRITERIA

The anticipated date of award is July 1, 1995. Awards will be made based on the following criteria: priority score, availability of funds, and programmatic priorities.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Marc Manley, M.D., M.P.H.
Division of Cancer Prevention and Control
National Cancer Institute
Executive Plaza North, Room 233
Bethesda, MD 20892
Telephone: (301) 496-8584
FAX: (301) 496-8675

Direct inquiries regarding fiscal matters to:

Marci Bollt
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800

AUTHORITIES AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.339. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52, 45 CFR Part 74, and 45 CFR Part 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

OBESITY/NUTRITION RESEARCH CENTERS

NIH GUIDE, Volume 23, Number 19, May 20, 1994

RFA AVAILABLE: DK-94-020

P.T. 04; K.W. 0710095, 0715145, 0710030, 1002004, 0765020

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: October 21, 1994

Application Receipt Date: November 22, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites applications for Obesity/Nutrition Research Centers (ORNCs) to conduct basic and clinical research on obesity, and the related fields of energy metabolism, body composition, satiety, adipocyte metabolism, eating disorders and weight management. This center will be awarded as a core center in Fiscal Year 1996. The award of at least one ONRC by NIDDK is anticipated.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention goals of "Healthy People 2000," a PHS-lead national activity for setting priorities. This RFA, Obesity/Nutrition Research Centers, is related to the priority areas of nutrition, physical activity and fitness, heart disease and stroke, cancer, diabetes, and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No 017-001-00474-0, or Summary Report: Stock No 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Minority individuals and women are encouraged to submit as principal investigators. Foreign institutions are not eligible to apply.

MECHANISM OF SUPPORT

Support of this program will be through the NIH core center (P30) award. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the PHS Grants Policy Statement. The earliest anticipated award date will be December 1, 1995.

FUNDS AVAILABLE

The NIDDK anticipates awarding one ONRC Grant in Fiscal Year 1996 on a competitive basis. The receipt of one competing continuation application is anticipated, which will be in competition with other applications received in response to this RFA. The anticipated award will be for five years and will be contingent upon the availability of appropriated funds. Each request for support must be limited to no more than \$700,000 in direct costs per year. Any application exceeding this amount will be returned to the applicant.

RESEARCH OBJECTIVES

The objectives of the Core Center are to encourage a multidisciplinary approach to research in the nutritional sciences and to bring together, on a cooperative basis, clinical and basic science investigators in a manner that will enhance and extend the effectiveness of nutritional research being conducted in the field of obesity, eating disorders, and energy regulation. To accomplish the overall goal of these centers, there must be in existence at the applicant's institution an ongoing program of excellence in biomedical research related to the study of obesity. This research should be in the form of NIH-funded research projects (R01), FIRST Awards (R29), program projects (P01) or other peer-reviewed research from Federal and non-Federal sources. The research base in the nutritional sciences need not be exclusively in obesity and can include a focus on eating disorders, energy metabolism, cell biology, or nutrient metabolism. It would be highly desirable that the Principal Investigator, as well as the applicant institution, have a commitment to the treatment and prevention of obesity. The availability of a clinic population with adequate representation of women and minorities that can be readily utilized by investigators will play a major role in attracting investigators to the field of obesity research and to serve as a resource in the design of pilot and feasibility projects.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent, by October 21, 1994. The letter of intent should include a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIDDK staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Review Branch
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 603
Bethesda, MD 20892

APPLICATION PROCEDURES

Applications are to be submitted using form PHS 398 (rev. 9/91), available in the office of sponsored research at most academic or research institutions and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. The RFA label available in the PHS 398 application form must be affixed to the bottom of the face page.

Applications must be received by November 22, 1994, the original and three copies of the application must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Two additional copies of the application, under separate cover, must be sent to:

Review Branch
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 603
Bethesda, MD 20892

REVIEW CONSIDERATIONS

Applications for a ONRC grant will be evaluated in national competition by the NIH grant peer review process. Applications will be reviewed initially by an ad hoc review group convened by the NIDDK and subsequently by the National Diabetes and Digestive and Kidney Diseases Advisory Council.

INQUIRIES

Applicants should request a copy of the RFA as well as a copy of "Guidelines for Obesity/Nutrition Research Centers". These guidelines contain important additional information of the format, content and review criteria. Prospective applicants may obtain guidelines from and may address inquiries to:

Van S. Hubbard, M.D., Ph.D.
Division of Digestive Diseases and Nutrition
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A18B
Bethesda, MD 20892
Telephone: (301) 594-7573
FAX: (301) 594-7504

Inquiries regarding fiscal matters may be directed to:

Ms. Trude McCain
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 653
Bethesda, MD 20892
Telephone: (301) 594-7543

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.847. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NATIONAL RESEARCH SERVICE AWARD INDIVIDUAL POSTDOCTORAL FELLOWSHIPS

NIH GUIDE, Volume 23, Number 19, May 20, 1994

PA NUMBER: PA-94-068

P.T. 22; K.W. 0720005, 0730050

Agency for Health Care Policy and Research

Application Receipt Dates: August 5, December 5, and April 5

PURPOSE

The Agency for Health Care Policy and Research (AHCPR) announces the continuing availability of postdoctoral National Research Service Award (NRSA) individual fellowships (F32) in health services research. These postdoctoral research fellowships provide opportunities for one or more years of academic training and supervised experience in applying quantitative research methods to the systematic analysis and evaluation of health services. Women, minorities, and individuals with disabilities are encouraged to apply.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. The AHCPR urges applicants to submit grant applications with relevance to the specific objectives of this initiative. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-004374-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY

Applicants for postdoctoral fellowships must, at the time they apply, be citizens of the United States, noncitizen nationals, or noncitizens who have been lawfully admitted to the United States for permanent residence and have in their possession an Alien Registration Receipt Card I-551 or I-151 or other legal verification of such status at the time of application. Individuals on temporary or student visas are not eligible.

Applicants must have received, by the activation date of the NRSA fellowship, a Ph.D., M.D., D.D.S., D.M.D., Sc.D., Dr.P.H., D.Pharm., or equivalent doctoral degree from an accredited domestic or foreign institution. Certification from an authorized official of the degree-granting institution that all degree requirements have been met is acceptable. (Persons possessing the J.D. degree as the sole advanced degree are not considered postdoctoral for NRSA purposes.)

NRSA fellowships may not be used to support studies leading to the M.D., D.O., D.D.S., D.M.D., or equivalent health professional degree nor do they support residency training.

MECHANISM OF SUPPORT

This program announcement (PA) uses the National Research Service Award individual postdoctoral fellowship (F32) mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant and the sponsoring institution. This program announcement replaces PA-92-08.

RESEARCH OBJECTIVES

AHCPR-sponsored NRSA fellowships emphasize multidisciplinary health services research training. This training should provide a rigorous conceptual and methodological foundation for investigating topics that include, but are not limited to, the following:

- o Determinants of successful health care market reform, including incentives for selection of efficient health plans by health care purchasers and effective management by health care providers;
- o Cost-effectiveness and cost-benefit analysis, including allocation of health care resources and its relationship to health status;
- o Analysis of service delivery, resource use, and costs of care for persons with HIV-related illnesses;
- o Primary care issues, including relationships between the structure and organization of service delivery, access to care, and costs and outcomes of care;
- o Evaluation of managed care and other approaches to organizing, financing, and reimbursing health care services;
- o Alternative delivery systems, providers, and practice patterns in long-term care including home and community-based care;
- o Medical treatment effectiveness issues, including evaluation of outcomes associated with the use of clinical practice guidelines;
- o Availability, accessibility, effectiveness, and quality of care for underserved populations such as low-income groups and minority populations;
- o Rural health issues, including primary care access, service delivery, technology diffusion, and supply of health professionals;

- o Medical malpractice and liability;
- o Appropriateness and effectiveness, including cost effectiveness, of alternative treatments and technologies;
- o Factors affecting dissemination and assimilation of health and clinical information to practitioners and patients;
- o Development of measures, methods, and technologies to support quality assurance and foster quality improvement in health care; and
- o Application of medical informatics to developing and improving expert systems for clinical diagnosis and treatment selection.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of AHCPR that women and members of minority groups must be included in all AHCPR supported health services research projects involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

A new NIH policy resulting from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) supersedes and strengthens NIH's previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which were in effect since 1990 and which AHCPR had adopted. The new NIH policy contains some provisions that are substantially different from the 1990 policies. AHCPR plans to publish guidelines specific to AHCPR. In the interim, AHCPR will follow the NIH guidelines, as applicable.

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the Federal Register of March 9, 1994 (FR 59 11146-11151) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994. Investigators also may obtain copies of the NIH policy from the AHCPR program staff listed under INQUIRIES. AHCPR program staff may also provide additional relevant information concerning this policy.

APPLICATION PROCEDURES

Prior to making formal application, an individual applicant must be accepted by an appropriate institution (private or public, for-profit or non-profit) and by a sponsor who will supervise the training and research experience. The applicant's research training plan should include a description of the proposed activities under the award and the aims, significance, and experimental design and methods of the research proposal. The sponsor must describe in detail the research training plan and the availability of suitable staff and facilities. Formal training is not necessarily limited to a single academic institution or discipline. The sponsor must be an established investigator who is active in health services research and who personally will supervise the applicant's training and research program.

Fellowship applicants requesting continued training at the doctorate institution or under the same sponsor in an institution where they have been training for more than a year should describe those opportunities for new or additional training experiences that will broaden the scientific background and perspective.

Applicants must submit the original and two copies of Public Health Service form PHS 416-1 (rev. 10/91), Individual National Research Service Award Application. If the applicant is lawfully admitted to the United States for permanent residence, a notarized statement documenting this status is required. NRSA fellowship material for AHCPR applications is available from Global Exchange Inc., 7910 Woodmont Ave. Suite 400, Bethesda, MD 20814-3015, telephone 301-656-3100 (FAX 301-652-5264).

Do not send applications to AHCPR. The completed, signed original application and two copies must be sent or delivered to:

Fellowship
Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

The following is the schedule for individual NRSA application receipt and review:

Application Receipt Date:	Aug 5	Dec 5	Apr 5
Study Section Review:	Oct	Feb	Jun
Earliest Notification of Award:	Dec	Apr	Aug
Earliest Possible Start Date:	Jan	May	Sep

Applications for NRSA fellowships will be reviewed by a review committee that includes consultants from appropriate scientific fields. The committee will use the following criteria in evaluating applications:

- o Applicant's past academic and research accomplishments;
- o Applicant's research and training goals and potential for a health services research career;
- o Research training program proposed (including the training potential, as well as the scientific merit of the research project);
- o Qualifications and suitability of the proposed sponsor and appropriateness of the institutional environment; and
- o References and other relevant information.

AWARD CRITERIA

For applications assigned to the AHCPR, awards will be made based on the recommendations of the review committee, relevance of the application to AHCPR research priorities and training needs, and availability of funds in making the final selection of awardees.

Stipends and Other Training Costs

A stipend is provided to each NRSA fellow to help defray living expenses during the research training experience. The stipend amount is determined by the number of full years of relevant postdoctoral experience as of the date the award is issued. Relevant experience may include research experience, teaching, internship, residency, or other time spent in full-time studies in a health-related field beyond that of the qualifying doctoral degree.

No departure from the standard stipend schedule may be negotiated between the institution and the fellow. Current postdoctoral stipend levels are listed below:

Full years of relevant experience	Annual stipend
None	\$19,608
1	20,700
2	25,600
3	26,900
4	28,200
5	29,500
6	30,800
7 or more	32,300

AHCPR will provide an allowance of \$3,000 per 12-month period to non-Federal, non-profit sponsoring institutions to cover such awardee expenses as tuition and fees, self-only health insurance, research supplies, equipment, travel to scientific meetings, and related items. There is no institutional allowance for individuals sponsored by for-profit institutions; but AHCPR will provide up to \$2,000 for the fellow's tuition and fees, self-only health insurance, scientific meeting travel expenses, and books. The \$2,000 is paid to the for-profit institution for disbursement to the fellow, and any unexpended funds are to be returned to AHCPR.

Additional funds may be requested by the institution for extraordinary costs for fellows who are disabled, as defined by the Americans with Disabilities Act. Such additional funds are provided only in exceptional circumstances and must be fully justified and explained by the institution.

Supplementation: Institutions may use non-Federal funds to supplement NRSA stipends. Federal funds may be used for stipend supplementation only if specifically authorized under the terms of the program from which the supplemental funds are derived. An individual may make use of Federal educational loan funds or VA benefits when permitted by these programs. Supplementation, when provided, must be without obligation to the trainee.

Compensation: Trainees may be permitted to receive compensation for work in some other position (for example, teaching or laboratory assistance) when the trainee is in an employee-employer relationship, the payments are for services rendered, and the situation otherwise meets conditions for student compensation as specified in the PHS Grants Policy Statement. Compensation may not be from a research grant that supports the same research that is part of the NRSA experience. Compensation for services must occur on a limited, part-time basis apart from the normal full-time training activities that require a minimum of 40 hours per week.

Under no circumstances may the conditions of either stipend supplementation or student compensation for coincidental employment detract from or prolong the research training. Further information on stipend supplementation and compensation is available in "National Research Service Awards -- Guidelines for Individual Awards - Institutional Grants," NIH Guide for Grants and Contracts (special edition), Volume 13, Number 1, January 6, 1984.

Conditions of the Award

Applications may be for one, two, or three years of fellowship support. No one is eligible for more than three years of aggregate NRSA support at the postdoctoral level, including any combination of support from institutional training grants and individual fellowships.

Fellowships are awarded for full-time research training. However, it is recognized that a close interrelationship between teaching and research may exist in the academic environment. Fellows are permitted, with the approval of the sponsor, to undertake teaching that can contribute meaningfully to their academic training. Any teaching undertaken by a fellow may not occupy more than 10 percent of work time during the year or exceed four hours per week. Fellows in clinical areas are expected to devote their time to the proposed research training program and to confine limited clinical duties to those that are part of the research training.

Concurrent awards: An NRSA postdoctoral fellowship may not be held concurrently with another federally sponsored fellowship or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA.

Activation: The awardee must start work on the fellowship within six months of the date the award is issued. No funds may be disbursed until the award is activated.

Tax liability of stipends: Section 117 of the Internal Revenue Code applies to the tax treatment of all scholarships and fellowships. It must be emphasized that the interpretation and implementation of tax laws are the domain of the Internal Revenue Service (IRS) and U.S. courts. AHCPR does not have the authority to advise students or institutions about their tax liability. The business office of the sponsoring institution is responsible for the annual preparation and issuance of the IRS Form 1099 for postdoctoral fellows training at the institution. Individuals should consult their

local IRS office for more detailed information on the proper steps to be taken regarding their tax obligations.

The taxability of stipends in no way alters the relationship between NRSA fellows and their institutions. NRSA stipends are not now, and never have been, salaries. Fellows supported under a National Research Service Award are not in an employer-employee relationship with AHCPR or with the institution in which they are pursuing research training. It is inappropriate and unallowable for institutions to seek funds or to charge individual fellowship awards for costs normally associated with employee benefits (such as FICA, workers' compensation, or unemployment insurance).

Termination and postaward reporting: At the conclusion of the fellowship, the fellow must submit a termination notice (form PHS 416-7) to AHCPR. NRSA fellowship recipients are responsible for informing AHCPR of changes in their status or address and for submitting the Annual Payback Activities Certification (form PHS 6031-1) yearly until any required payback service obligation is satisfied.

Payback provision: Before an award is made, the fellow must sign an agreement to fulfill the congressionally mandated payback requirements. The NIH Revitalization Act of 1993 substantially modifies the existing service payback requirements for individuals supported under NRSA programs. For fellowship awards beginning after June 10, 1993, only fellows in the first 12 months of postdoctoral NRSA support will incur a service obligation of one month for each month of support. Postdoctoral fellows in the 13th and subsequent months of NRSA support will not sign the Payback Agreement Form (Form PHS 6031) and will incur no further obligation.

The 13th and each subsequent month of postdoctoral NRSA support will be considered acceptable payback service; therefore, individuals who begin the initial postdoctoral fellowship on or after June 10, 1993, and continue under that award for two years will have fulfilled their first year obligation by the end of the second year of training.

Service payback obligations can also be repaid after the period of training by engaging in health services related research (including research assistantships/associateships and fellowships) and/or teaching for at least 20 hours per week averaged over a full year. Positions after training are arranged by the individual, not AHCPR.

Recipients must undertake the obligated service on a continuous basis within two years after termination of NRSA support. The period for undertaking payback service may be delayed for temporary disability, for completion of residency requirements, or for completion of the requirements for a graduate degree. Requests for an extension must be made in writing to AHCPR and must specify the need for additional time and the length of the required extension.

Individuals who fail to fulfill any required obligation through service must pay back the total amount of NRSA funds paid to them for the obligation period plus interest at a rate determined by the Secretary of the Treasury. Financial payback must be completed within three years beginning on the date the United States becomes entitled to recover such amount.

Under certain conditions, the Secretary of Health and Human Services may extend the period for starting service or for repayment, permit breaks in the period of service or repayment, or otherwise waive or suspend the payback obligation of an individual.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Direct inquiries regarding programmatic issues to:

DonnaRae Castillo
NRSA Project Officer
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 501
Rockville, MD 20852
Telephone: (301) 594-1362

Direct inquiries regarding fiscal and administrative matters to:

Ralph Sloat
Grants Management Officer
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 601
Rockville, MD 20852
Telephone: (301) 594-1447

AUTHORITY AND REGULATIONS

NRSA individual postdoctoral fellowships are made under authority of Section 487 of the Public Health Service Act, as amended (42 USC 288). Title 42 of the Code of Federal Regulations, Part 66, is applicable to this program. The program is described under Catalog of Federal Domestic Assistance No. 93.225 and is not subject to the intergovernmental review requirements of Executive Order 12372.

****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

5333 Westbard Avenue
Bethesda, MD 20816



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For Grants and Contracts

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Vol. 23, No. 20
May 27, 1994

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

THE PUBLIC HEALTH SERVICE (PHS) STRONGLY ENCOURAGES ALL GRANT RECIPIENTS TO PROVIDE A SMOKE-FREE WORKPLACE AND PROMOTE THE NON-USE OF ALL TOBACCO PRODUCTS. THIS IS CONSISTENT WITH THE PHS MISSION TO PROTECT AND ADVANCE THE PHYSICAL AND MENTAL HEALTH OF THE AMERICAN PEOPLE.

NOTICES

NIH GUIDE FOR GRANTS AND CONTRACTS ELECTRONIC DISTRIBUTION LIST

NIH GUIDE, Volume 23, Number 20, May 27, 1994

P.T. 16; K.W. 1004017

National Institutes of Health

There have been two changes in the LISTSERV distribution of the NIH Guide:

1. NIHGDE-L is now an open list.

The NIHGDE-L list is now open for subscriptions from individuals. To minimize the possibility of errors, it is best for each person to subscribe him/herself to the list. Subscribing and unsubscribing to/from a list is done via e-mail. BITNET users should send mail to LISTSERV@JHUVUM, and Internet users to LISTSERV@JHUVUM.HCF.JHU.EDU. To subscribe to the E-Guide list, the text of the mail should be:

SUBSCRIBE NIHGDE-L First-name Last-name

The First & Last names should be in upper & lower case; e.g.:

SUBSCRIBE NIHGDE-L Bill Jones

This will register the e-mail address from which the mail was sent for E-Guide distribution. If you wish to have the E-Guide sent to an address from which mail cannot be sent (e.g., an internal distribution list), send mail to WKJ@NIHCU (BITNET) or WKJ@CU.NIH.GOV (Internet). To remove yourself from this list, send mail to LISTSERV@JHUVUM (or LISTSERV@JHUVUM.HCF.JHU.EDU) containing as the text:

UNSUBSCRIBE NIHGDE-L

2. Table of Contents list established.

Some users who subscribed to the NIHGDE-L list had problems with the volume of mail that was received each week. They would prefer to see a table of contents, and access the NIH Guide files via Gopher when necessary. For that purpose, the NIHTOC-L list has been established at the NIH. It will contain only the table of contents for each week's NIH Guide. It is an open list that one can subscribe to by sending mail to LISTSERV@NIHLIST or LISTSERV@LIST.NIH.GOV (Internet). The mail should contain as text:

SUBSCRIBE NIHTOC-L First-name Last-name

If you do subscribe to the NIHTOC-L list and are already subscribed to the NIHGDE-L list, you will probably want to UNSUBSCRIBE from that list.

INQUIRIES

Myra Brockett
Institutional Affairs Office
National Institutes of Health
Building 1, Room 328
Bethesda, MD 20892
Email: Q2C@NIHCU or Q2C@CU.NIH.GOV

NATIONAL HUMAN SUBJECT PROTECTIONS WORKSHOPS

NIH GUIDE, Volume 23, Number 20, May 27, 1994

P.T. 42; K.W. 0783005

National Institutes of Health
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

DATES: July 11, 12, 13, 1994

LOCATION

Mall of American Grand Hotel, Bloomington, MN

SPONSORS

University of Minnesota of Minneapolis, Minneapolis, MN
American Indian Health Care Association, St. Paul, MN
Indian Health Service, Albuquerque, NM
Office of Research on Minority Health, NIH, Bethesda, MD

CONTACT

Office of Continuing Medical Education
University of Minnesota
Radisson Hotel Metrodome, Suite 107
615 Washington Avenue, SE
Minneapolis, MN 55414
Telephone: (612) 626-7600 or (800) 776-8636

TITLE: Contemporary Issues on Existing and New Research Guidelines on Women and Minority Groups: Special Emphasis on American Indians

DESCRIPTION: The Conference will examine existing NIH research guidelines, and discuss contemporary issues in the research environment. There will be IRB training; conference participants will be in small mock IRBs to review three protocols, with facilitation by experienced IRB staff. The Conference will examine how protecting American Indian individuals and communities by IRBs and community participation: (1) increases research benefit, (2) decreases research risk, and (3) improves quality of the research. Because Native (American Indian and Canadian First Nation) people are covered by the new NIH guidelines about inclusion of women and minorities in research, the Conference will also examine that policy in depth. The focus on Native communities and volunteers will illuminate how the new Guidelines, current IRB regulations, and community involvement fit together in practice.

INQUIRIES

For further information regarding these workshops or future NIH/FDA National Human Subject Protections Workshops, contact:

Ms. Darlene M. Ross
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 5B63
Bethesda, MD 20892
Telephone: (301) 496-8101

SPECIALIZED CENTERS OF RESEARCH IN PATHOBIOLOGY OF FIBROTIC LUNG DISEASE, PATHOBIOLOGY OF LUNG DEVELOPMENT, AND CELLULAR AND MOLECULAR MECHANISMS OF ASTHMA

NIH GUIDE, Volume 23, Number 20, May 27, 1994

RFA AVAILABLE: HL-94-008

P.T. 04; K.W. 0715013, 0715165, 1002008, 0765035

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: December 15, 1994

Application Receipt Date: July 14, 1995

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACTS LISTED BELOW IN "INQUIRIES." FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The primary objective of the Specialized Centers of Research (SCORs) programs supported by the Division of Lung Diseases is to foster multidisciplinary basic and clinical research enabling basic science findings to be more rapidly applied to clinical problems. The basic and clinical research to be supported through this RFA will be related to one of the above three categories. It is expected that results from these SCOR grants will have an impact on the prevention, diagnosis, and treatment of fibrotic lung disease, pulmonary diseases in infants and children, and asthma.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, SCORs in Pathobiology of Fibrotic Lung Disease, Pathobiology of Lung Development, and Cellular and Molecular Mechanisms of Asthma, is related to the priority areas of occupational safety and health, environmental health, maternal and infant health, diabetes and chronic disabling diseases, and immunization and infectious diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by for-profit and non-profit domestic institutions, public and private, such as universities, colleges, hospitals, and laboratories. This RFA is intended to support SCOR grants for basic and clinical investigations; therefore, applications that include only basic or only clinical research will not be responsive. In addition, clinical research projects focused on large epidemiologic studies or large clinical trials will be considered unresponsive to this RFA. Awards will not be made to foreign institutions. However, under exceptional circumstances, a foreign component critical to a project may be included as a part of that project. Women and minority investigators are encouraged to apply.

MECHANISM OF SUPPORT

This RFA will use the National Heart, Lung, and Blood Institute (NHLBI) SCOR (P50) grant to support this research program. All applications received in response to this solicitation will be considered as new applications. Applications submitted by current SCOR groups must be sufficiently changed to meet the objectives of one of the three programs described in this RFA. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. All current policies and requirements that govern the research grant programs of the NIH will apply to grants awarded under this RFA.

Basic and Clinical Research

It is essential that all applications include both basic and clinical research projects. Interactions between basic and clinical scientists are expected to strengthen the research, enhance transfer of fundamental research findings to the clinical setting, and identify new research directions.

FUNDS AVAILABLE

Applicants may request up to \$1,170,000 direct costs, not including indirect costs for collaborating institutions, in the first year with a maximum increase of no more than 4 percent in each additional year requested in the application. Award of grants pursuant to this RFA is contingent upon availability of funds for this purpose. It is estimated that a total of \$28,000,000 will be available for the first year of support for the three programs and it is anticipated that 14 awards will be made.

RESEARCH OBJECTIVES

Background

A SCOR grant is a five-year program, therefore, an applicant should submit a five-year plan for all the projects. If a project can be completed in less than five years, it should not be included in the application. Applications must be addressed to only one of the following three disease categories to be acceptable for this competition.

- a. Pathobiology of Fibrotic Lung Disease
- b. Pathobiology of Lung Development
- c. Cellular and Molecular Mechanisms of Asthma

Further discussion of each research topic of interest is provided in the RFA. It is not required that all or any of these topics be included; investigators are encouraged to consider other topics that are relevant to the goals of these programs.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by December 15, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it assists the NHLBI staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Chief, Review Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 557
Bethesda, MD 20892

REVIEW CONSIDERATIONS

Applications will be judged on the basis of the scientific and technical merit of the proposed research, the qualifications and research experience of the investigators, the collaborative interaction among basic and clinical research components, the adequacy of the environment, and the appropriateness of the budget.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research or may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Room 449, Bethesda, MD 20892, telephone 301/594-7248.

Applications must be received by July 14, 1995.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct inquiries regarding programmatic issues and requests for the RFA to:

Suzanne Hurd, Ph.D.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 6A16
Bethesda, MD 20892
Telephone: (301) 594-7430
FAX: (301) 594-7408

Direct inquiries regarding fiscal and administrative matters to:

Mr. Raymond Zimmerman
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A17
Bethesda, MD 20892
Telephone: (301) 594-7420
FAX: (301) 594-7492

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.838. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 2241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NATIONAL RESEARCH SERVICE AWARD - SENIOR FELLOWSHIPS

NIH GUIDE, Volume 23, Number 20, May 27, 1994

PA NUMBER: PAR-94-069

P.T. 22; K.W. 0715148, 0720005

National Institute of Dental Research

PURPOSE

The National Institute of Dental Research (NIDR) invites applications for National Research Service Award (NRSA), Senior Fellowships (F33). The objective is to provide mentored research training for experienced scientists, committed to broadening their scientific background by acquiring new oral health research capabilities, to make major changes in the direction of their research careers. These fellowships enable such scientists to take time from regular professional responsibilities for the purpose of receiving training to increase their ability to engage in oral health research. They are not intended for investigators to prove their research potential.

The training and research must be relevant to the goals of the NIDR including: research on the causes, epidemiology, prevention, diagnosis and treatment of dental caries, periodontal and soft tissue diseases, oral cancer, oral manifestations of AIDS, and craniofacial anomalies; orofacial pain; temporomandibular disorders; structure and function of teeth, jaws, oral mucosa, bone, connective tissue, salivary glands; behavioral, social, economic and cultural factors related to oral diseases and disorders; biomaterials; fluoride and nutrition; and research on older Americans, gender differences, minorities, those with medical problems and handicaps, and individuals and groups at high-risk for oral health problems.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement (PA), NRSA - Senior Fellowship Applications, is related to the priority area of oral health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, public, and private institutions such as dental schools, dental research institutions, and universities, on behalf of applicants. Applicants must have received a Ph.D., D.D.S., D.M.D., or equivalent degree from an accredited domestic or foreign institution and must have had at least seven subsequent years of relevant research experience. Applications from minorities and women are encouraged.

Applicants must be citizens or non-citizen nationals of the United States or have been lawfully admitted for permanent residence (i.e., in possession of the Alien Registration Receipt Card I-551 or I-151) at the time of appointment. Individuals on temporary or student visas are not eligible. Non-citizen nationals, although not citizens of the United States, owe permanent allegiance to the U.S. They are generally born in lands that are not states but are under U.S. sovereignty, jurisdiction, or administration. Dentists on temporary or student visas are not eligible.

MECHANISM OF SUPPORT

Awards in response to this PA will be the National Institutes of Health (NIH), NRSA Senior Fellowship (F33). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant and sponsor.

RESEARCH OBJECTIVES

Background

Rapid advances in all aspects of oral health research and the increasingly sophisticated technology required for investigators to maintain the pace of research may lead to obsolescence of their skills. The half-life of principal investigators supported by the NIH decreased progressively from approximately 12 years in 1970 to five years by the mid-nineteen eighties. The number of research grant applications submitted to the NIH by the 35 to 45 year old age group was twice that of the 46 to 55 year old group and the 34 years and younger group, while the success rates in obtaining funding were similar. The more mature investigators may go on to productive careers in some other segment of the academic, government, or industrial communities, but the relatively brief research careers of these highly trained individuals represents a major loss to the research enterprise.

Most attempts to maintain a large enough pool of active investigators have concentrated on attracting and training young people. Retraining of proven productive investigators to enable them to continue as actively contributing members of the research community can be a highly efficient way to maintain the competence of the research labor force. The Senior Fellowship, frequently used in conjunction with sabbatical support from the home institution, provides a viable mechanism to enable faculty or staff to refurbish their skills and continue productively for the full duration of their careers.

Program Characteristics

The training program must provide opportunities for an established investigator to carry out mentored biomedical or behavioral oral health research, expand the fellow's knowledge, and develop new research skills.

Before submitting an application, an individual must arrange for acceptance by an institution and sponsor, who will serve as a mentor. The institutional setting may be a non-profit or public institution, including a federal laboratory. Individuals requesting foreign training must provide justification based on the nature of the facilities and/or training opportunity, and of the unique aspects of the foreign, rather than domestic, site for the proposed research. Only in cases where there are clear scientific advantages will foreign training be supported.

The total support period may not exceed two years; awards are not renewable. No individual may receive more than three years of aggregate postdoctoral NRSA support, including any combination of individual and institutional awards, without a waiver from the NIH. Where needed, the application should be accompanied by a letter requesting a waiver of the three-year limit. The proposed training must be full-time and include research under a mentor who is an established investigator. The award may not be used to support studies leading to a D.D.S. or other similar professional degrees or to support residencies or other postgraduate training providing health care directly to patients, where the majority of time is spent in non-research clinical training.

Stipends and Other Training Costs

For senior fellows, the stipend is determined individually at the time of appointment. The amount of the stipend shall be based on the salary or remuneration which the individual would have been paid on the date of the award from their home institutions, but in no case shall the NIDR stipend exceed \$32,300 per year, prorated on a monthly basis for less than 12-month awards.

The stipend is not provided as a condition of employment by either the Federal Government or the institution. Fringe benefits are not provided by this award. No allowance will be provided for dependents or for an individual's travel to a domestic training site. Individuals affiliating with foreign sponsoring institutions will be provided a single economy or coach round-trip fare to the training site. U.S. flag air carriers must be used to the maximum extent possible when commercial air transportation is the means of travel between the United States and a foreign country or between foreign countries.

The Tax Reform Act of 1986, Public Law 99-514, impacts on the tax liability of all individuals supported under the NRSA program. Senior fellows will be required to report stipends and all monies paid on their behalf for tuition and fees. The NIH is not in a position to advise fellows or institutions about their tax liability. Changes in the taxability of stipends in no way alters the relationship between NRSA fellows and institutions. NRSA stipends are not now, and never have been, salaries. Fellows supported under the NRSA are not in an employer-employee relationship with the NIH or the institution at which they are pursuing research training.

Stipends may be supplemented by an institution from non-Federal funds. Other NIH funds may not be used to supplement stipends. Non-NIH Federal funds may not be used for stipend supplementation unless specifically authorized under the terms of the program from which the supplemental funds are derived. An individual may make use of Federal educational loan funds or Department of Veterans' Affairs benefits when permitted by those programs. Under no circumstance may the condition of stipend supplementation detract from or prolong the training.

The NIDR will provide funds of up to \$3,000 per 12-month period to nonfederal sponsoring institutions to help defray awardee expenses such as tuition and fees, individual health insurance, research supplies, equipment, travel to scientific meetings and related items. An allowance of up to \$2,000 is available for individuals sponsored by federal laboratories for scientific meeting travel expenses, individual health insurance, and tuition and fees. For award periods of less than 12 months, these allowances will be prorated on a monthly basis.

Payback Provisions

Senior fellows must sign an agreement to fulfill NRSA payback requirements. They incur payback obligation for the first twelve months of support. This obligation will be satisfied by continuing on the fellowship for an additional 12 months. For payback obligations that are not satisfied in this way, fellows must engage in biomedical or health-related behavioral research and/or teaching for a period equal to the period of support up to 12 months. The obligated service must be undertaken continuously within two years after termination of support. Individuals who fail to fulfill the obligation through service must pay back the total amount of funds paid to the individual for the obligation period plus interest at a rate determined by the Secretary of the Treasury. Financial payback must be completed within three years of the date the United States becomes entitled to recover such amount.

Under certain conditions, the Secretary of Health and Human Services may extend the period for starting service or for repayment, permit breaks in the period of service or repayment, or otherwise waive or suspend the payback obligation of an individual.

Officials of the applicant organization should familiarize themselves with the terms of the payback service requirement and explain them carefully to prospective fellows before an appointment is offered. For additional information, including the grounds for approving extensions of support and payback provisions, refer to the announcements in the NIH Guide, "National Research Service Awards - Guidelines for Individual Awards - Institutional Grants," Special Edition, Volume 13, No. 1, January 6, 1984, and "Modification of the NRSA Service Payback Obligation," Volume 22, No. 27, July 30, 1993.

APPLICATION PROCEDURES

It is strongly recommended that prospective applicants contact Dr. Thomas M. Valega, at the address listed under INQUIRIES, early in the planning phase of application preparation. This will help ensure that applications are responsive to the PA. Applicants must allow at least eight months between the submission date and the date of an award.

Applications must be submitted on form PHS 416-1 (rev. 10/91) and received by the established receipt dates: August 5, December 5, and April 5. Application forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from Dr. Valega at the address listed under INQUIRIES.

The applicant must provide information establishing a serious, continued commitment to oral health research, summarize career objectives, and explain how the award would contribute to their attainment. Applications for NRSA (F33) awards must include three sealed letters of reference, addressing the applicant's potential for continuing a productive research career, attached to the face page of the original application. NRSA (F33) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

To identify the application as a response to this PA, check "YES" on item 2a of page 1 of the application and enter "PAR-94-069, NRSA - Senior Fellowship."

Submit a signed, typewritten original of the application, including the Checklist, three signed, photocopies, and the letters of recommendation, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892-4500**

The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Applications will be reviewed for completeness by DRG staff. Incomplete or applications will be returned to the applicant without further consideration. The review criteria outlined in form PHS 416-1 will be applied. They focus on the applicant's qualifications and commitment to continuing a career in oral health research, the research proposal, resources including the sponsor, and the training environment. Secondary review of applications assigned to the NIDR will be by the NIDR Extramural Staff Review Committee.

AWARD CRITERIA

For applications assigned to the NIDR, staff will notify the applicant of the Extramural Staff Review Committee's action shortly after its meeting. Funding decisions will be made based on the Committees' recommendations; the need for research personnel in particular program areas; and the availability of funds.

The NIDR appreciates the value of complementary funding from other public and private sources, including foundations and industrial concerns, for activities that will complement and expand those supported by the NIDR.

INQUIRIES

Written and telephone inquiries concerning this PA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues and address letter of intent to:

Thomas M. Valega, Ph.D.
Extramural Program
National Institute of Dental Research
Westwood Building, Room 503
Bethesda, MD 20892
Telephone: (301) 594-7617
FAX: (301) 594-7616

Direct inquiries pertaining to fiscal matters to:

Theresa Ringler
Extramural Program
National Institute of Dental Research
Westwood Building, Room 510
Bethesda, MD 20892
Telephone: (301) 594-7629

AUTHORITY AND REGULATIONS

NRSA Senior Fellowships are made under the authority of Section 487 of the Public Health Service (PHS) Act as amended (42 USC 288). Title 42 of the Code of Federal Regulations, Part 66, is applicable to this program. This program is also described in the Catalog of Federal Domestic Assistance No. 93.121. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

UTERINE BLEEDING AND STEROID HORMONES

NIH GUIDE, Volume 23, Number 20, May 27, 1994

RFA AVAILABLE: HD-94-023

P.T. 34; K.W. 0710110, 0760085

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: June 8, 1994

Application Receipt Date: August 19, 1994

The following change is made to RFA HD-94-023, which was published in the NIH Guide for Grants and Contracts, Vol. 23, No. 16, April 29, 1994:

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Minority individuals, persons with disabilities, and women are encouraged to apply.

For further information, contact:

Nancy J. Alexander, Ph.D.
Center for Population Research
National Institute of Child Health and Human Development
Building 6100, Room 8B13
Bethesda, MD 20892
Telephone: (301) 496-1661
FAX: (301) 496-0962

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

***5333 Westbard Avenue
Bethesda, MD 20816***



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Vol. 23, No. 21
June 3, 1994

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NATIONAL RESEARCH SERVICE AWARD INSTITUTIONAL RESEARCH TRAINING GRANTS

NIH GUIDE, Volume 23, Number 21, June 3, 1994

P.T. 44; K.W. 0720005, 0710030

National Institutes of Health

PURPOSE

The National Institutes of Health (NIH) will award National Research Service Award (NRSA) institutional training grants (T32) to eligible institutions to develop or enhance research training opportunities for individuals, selected by the institution, who are training for careers in specified areas of biomedical and behavioral research. The purpose of the NRSA program is to help ensure that highly trained scientists are available in adequate numbers and in the appropriate research areas and fields to carry out the nation's biomedical and behavioral research agenda.

LEVELS OF TRAINING

The NRSA program supports both predoctoral and postdoctoral research training.

Predoctoral: Predoctoral research training must lead to the Ph.D. or a comparable research doctorate degree. Students enrolled in health-professional programs that are not part of a formal, combined program (i.e. M.D./Ph.D.) and who wish to postpone their professional studies in order to gain research experience may also be appointed to a T32. Predoctoral research training must emphasize fundamental training in areas of basic biomedical and behavioral sciences.

Postdoctoral: Postdoctoral research training is for individuals who have received a Ph.D., an M.D. or comparable doctoral degree from an accredited domestic or foreign institution. Comparable doctoral degrees include, but are not limited to the following: D.D.S., D.O., D.V.M., O.D., D.P.M., Sc.D., Eng.D., Dr. P.H., D.N.Sc., D. Pharm., D.S.W., and Psy.D. Research training at the postdoctoral level must emphasize specialized training to meet national research priorities in the biomedical and behavioral sciences.

Research training grants are a desirable mechanism for the postdoctoral training of physicians and other health professionals who may have had extensive clinical training, but limited research experience. For such individuals, the training may be a part of a research degree program; in all cases, health-professional postdoctoral trainees should agree to engage in at least two years of research, research training, or comparable experiences beginning at the time of appointment.

Short-Term Research Training Positions for Health-Professional Students: T32 applications, may include a request for short-term positions reserved specifically to train medical or other health-professional students on a full-time basis during the summer or other "off quarter" periods. Short-term appointments are intended to provide health-professional students with opportunities to participate in biomedical and/or behavioral research in an effort to attract these individuals into research careers.

Short-term positions should be longer than two months but may not last longer than three months. Students should be encouraged to obtain two or more periods of short-term research training during their studies leading to a health professional degree. Such appointments may be consecutive or may be reserved for summers or other "off quarter" periods.

Since some NIH Institutes support short-term research training positions on a limited basis, applicants are strongly urged to contact the appropriate NIH institute representative listed at the end of this announcement, before requesting short-term research training positions in a T32 application.

APPLICANT ELIGIBILITY REQUIREMENTS

Only domestic, non-profit, private or public institutions may apply for grants to support research training programs. The applicant institution must have the staff and facilities required for the proposed program. The research training program director at the institution will be responsible for the selection and appointment of trainees to receive NRSA support and for the overall direction of the program.

Trainees appointed to the training program must have the opportunity to carry out supervised biomedical or behavioral research with the primary objective of developing or extending their research skills and knowledge in preparation for a research career.

GENERAL PROVISIONS

Positions on NRSA institutional grants may not be used for study leading to the M.D., D.D.S., or other clinical, health-professional degrees except when those studies are a part of a formal combined research degree program such as the M.D./Ph.D. Similarly, trainees may not accept NRSA support for studies which are a part of residency training leading to a medical specialty or subspecialty except when the residency program credits a period of full-time, postdoctoral research training toward board certification and the trainee intends to pursue a research career.

Students enrolled in health-professional doctoral degree programs may receive support for short-term research training for one or more periods lasting up to three months each. Such students may also interrupt their studies for a year or more to engage in full-time research training before completing their professional degree.

Trainees are required to pursue their research training on a full-time basis, devoting at least 40 hours per week to the program. Within the 40 hours per week training period, research trainees in clinical areas must devote their time to the proposed research training and must confine clinical duties to those that are an integral part of the research training experience.

TRAINEE ELIGIBILITY REQUIREMENTS

To be appointed to a research training grant, an individual must be a citizen or a non-citizen national of the United States or must have been lawfully admitted for permanent residence (i.e., in possession of a currently valid Alien Registration Receipt Card I-551, or must be in possession of other legal verification of such status). Individuals on temporary or student visas are not eligible.

Predoctoral Trainees: Predoctoral trainees must have received a baccalaureate degree by the beginning date of their NRSA appointment, and must be training at the postbaccalaureate level in a program leading to the Ph.D. in science or in an equivalent research doctoral degree program. Health-professional students who wish to interrupt their studies for a year or more to engage in full-time research training before completing their professional degrees are also eligible.

Postdoctoral Trainees: Postdoctoral trainees must have received, as of the beginning date of the NRSA appointment, a Ph.D., M.D. or comparable doctoral degree from an accredited domestic or foreign institution. Written certification by an authorized official of the degree-granting institution that all degree requirements have been met, prior to the date training is to begin, is acceptable.

Short-Term Health Professional Trainees: To be eligible for short-term research training positions, health-professional students must have completed at least one quarter in a program leading to a clinical doctorate prior to participating in the program. Individuals matriculated in a formal research degree program or those holding an M.S., a Ph.D., or an M.D./Ph.D. degree or equivalent graduate level research degree are not eligible for short-term training positions. Within schools of pharmacy, only individuals who are candidates for the Pharm.D. degree are eligible for short-term positions.

DURATION OF SUPPORT

Institutional NRSA research training grants may be made for periods up to five years and are renewable.

Trainee appointments are normally made in 12-month increments with support for additional years dependent on satisfactory progress and the continued availability of funds.

No trainee may be appointed for less than nine months during the initial period of appointment, except with the prior approval of the NIH awarding unit or when health-professional students are appointed to approved, short-term research training positions. No individual trainee may receive more than five years of aggregate NRSA support at the predoctoral level or three years of aggregate NRSA support at the postdoctoral level, including any combination of support from institutional training grants and individual fellowship awards. Any exception to the total duration of trainee support at either the predoctoral or postdoctoral level requires a waiver from the Director of the awarding component at the NIH. The grounds for approving extension of support can be found in the current Guidelines for National Research Service Awards for Individual Awards and Institutional Grants.

RECRUITMENT AND APPOINTMENT OF TRAINEES

The primary objective of the NRSA program is to prepare qualified individuals for careers in biomedical and behavioral research. Within the framework of the program's longstanding commitment to excellence and projected needs for investigators in particular areas of research, it is important that attention also be given to recruiting individuals from minority groups that are underrepresented nationally in the biomedical and behavioral sciences. The following groups have been shown to be underrepresented in biomedical and behavioral research nationally: African Americans, Hispanics, Native Americans, Alaskan Natives, and Pacific Islanders. Future use of the term "minority" in this announcement will refer to these groups.

Other considerations relate to the duration of training and the movement of trainees to individual support mechanisms. Studies have shown that the length of the appointment to a training grant for postdoctoral trainees with health-professional degrees is strongly correlated with subsequent application for and receipt of independent NIH research support. Program directors, therefore, are strongly encouraged to limit appointments to individuals who plan to remain on the grant or in some other type of research experience for a minimum of two years. It has also been shown that individuals who have been supported by an individual postdoctoral fellowship are more likely to apply for and receive NIH research support than individuals who have received support from a training grant alone. Program directors are therefore encouraged to identify candidates for individual postdoctoral fellowships or early career development (K) awards in order to stimulate applications. During the review of applications, peer reviewers will examine the training record to determine how long health-professional postdoctoral trainees engage in research training and whether postdoctoral trainees have been successful in applying for individual training support.

Past studies have shown that trainees from programs oriented exclusively toward health-professionals are less likely to apply for and receive research grant support than health-professionals who train alongside postdoctoral researchers with a Ph.D. degree. Programs that focus on research training for individuals with an M.D. or other health-professional degrees should consider developing strong ties to basic science departments or modifying their program to include individuals with a Ph.D. degree if such changes are consistent with the goals of the program. Applications should describe the contribution of basic science departments to the research training experience and indicate also if both M.D. and Ph.D. trainees are included in the training program.

PAYBACK PROVISIONS

All postdoctoral trainees must sign an agreement to fulfill the NRSA payback requirements when they are appointed initially to a research training grant or receive an individual fellowship.

The NIH Revitalization Act of 1993 substantially modified the service payback requirement for individuals supported by the NRSA program. Beginning with appointments and reappointments made on or after June 10, 1993, the following guidelines apply:

- o Predoctoral trainees are not required to sign the Payback Agreement Form (PHS Form 6031) and do not incur a service payback obligation.
- o Postdoctoral trainees in the first twelve months of postdoctoral NRSA support must sign the payback agreement form and incur one month of obligation for each month of support.
- o Postdoctoral trainees in the thirteenth and subsequent months of NRSA support are not required to sign the Payback Agreement Form and do not incur a service payback obligation.
- o The thirteenth and subsequent months of postdoctoral NRSA support are considered acceptable payback service for prior postdoctoral support. Individuals appointed to their initial NRSA postdoctoral period on or after June 10, 1993, and who continue under that award for two years, have fulfilled their obligation by the end of the second year. Service payback obligations can also be paid back by conducting health-related research or teaching for more than 20 hours per week for a full year.

Recipients must begin to undertake any remaining obligated service on a continuous basis within two years after termination of NRSA support. The period for undertaking payback service may be delayed for such reasons as temporary disability, completion of residency requirements, or completion of the requirements for a graduate degree. Requests for an extension must be made in writing to the awarding unit specifying the need for additional time and the length of the required extension. Recipients of NRSA support are responsible for informing the awarding unit of changes in status or address. For individuals who fail to fulfill their obligation through service, the United States is entitled to recover the total amount of NRSA funds paid to the individual for the obligated period plus interest at a rate determined by the Secretary of the Treasury. Financial payback must be completed within three years beginning on the date the United States becomes entitled to recover such amount. Under certain conditions, the Secretary, Health and Human Services may extend the period for starting service or repayment, permit breaks in service, or otherwise waive or suspend the payback obligation of an individual.

STIPENDS

National Research Service Awards provide funds, in the form of stipends, to graduate students and postdoctoral researchers. A stipend is provided as a subsistence allowance for trainees to help defray living expenses during the research training experience. It is not provided as a condition of employment with either the Federal Government or the awardee institution.

Predoctoral: The current annual stipend for predoctoral trainees is \$10,008. For appointments of less than a year, the stipend will be based on a monthly proration that is currently \$834 per month.

Postdoctoral: The current annual stipend for postdoctoral trainees is determined by the number of FULL years of relevant postdoctoral experience at the time of appointment. Relevant experience may include research experience (including industrial), teaching, internship, residency, clinical duties, or other time spent in full-time studies in a health-related field following the qualifying doctoral degree. The stipend for each additional year of NRSA support is the next level on the stipend scale. Current postdoctoral stipends are as follows:

Years of Relevant Experience	Stipend
Less than 1	\$19,608
1	20,700
2	25,600
3	26,900
4	28,200
5	29,500
6	30,800
7 or more	32,300

A trainee with a health-professional doctoral degree who is enrolled in a graduate degree program is considered to be in postdoctoral training and will receive the appropriate postdoctoral stipend listed above.

No departure from the established stipend schedule may be negotiated by the institution with the trainee. The stipend for each additional full year of stipend support is the next level in the stipend structure and does not change mid-year. The sponsoring institution is allowed to provide funds to an individual in addition to the stipends paid by the NIH. Such additional amounts may be either in the form of augmented stipends (supplementation) or in the form of compensation, such as salary or tuition remission for services such as teaching or serving as a laboratory assistant, provided the following conditions are met:

Stipend Supplementation: Supplementation or additional support to offset the cost of living may be provided by the awardee institution but must not require any additional obligation from the trainee. Federal funds may not be used for supplementation unless specifically authorized under the terms of both the program from which such supplemental funds are to be received and the program whose funds are to be supplemented. Under no circumstances may PHS funds be used for supplementation.

Compensation: An institution may provide additional funds to a trainee in the form of compensation (as salary and/or tuition remission) for services such as teaching or serving as a laboratory assistant. A trainee may receive compensation for services as a research assistant or in some other position on a Federal research grant, including a PHS research grant. However, compensated services should occur on a limited, part-time basis apart from the normal research training activities, which require a minimum of 40 hours per week. In addition, compensation may not be paid from a research grant that supports research that is part of the research training experience.

Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the trainee's approved NRSA training program.

Educational Loans or G.I. Bill: An individual may make use of Federal educational loan funds and assistance under the Veterans Readjustment Benefits Act (G.I. Bill). Such funds are not considered supplementation or compensation.

Concurrent Awards: An NRSA may not be held concurrently with another Federally sponsored fellowship or similar award that provides a stipend or otherwise duplicates provisions of the NRSA.

More specific information on stipend supplementation and compensation is available in the current Guidelines for NRSA Individual Awards - Institutional Grants and in the current PHS Grants Policy Statement.

TAX LIABILITY

Section 117 of the Internal Revenue Code applies to the tax treatment of all scholarships and fellowships. Under that section, non-degree candidates are required to report all stipends, and any monies paid on their behalf for course tuition and fees required for attendance as gross income. Degree candidates may exclude from gross income (for tax purposes) any amount used for tuition and related expenses such as fees, books, supplies, and equipment required for courses of instruction at a qualified educational organization.

The taxability of stipends, however, in no way alters the relationship between NRSA trainees and institutions. NRSA stipends are not considered salaries. In addition, trainees supported under the NRSA are not considered to be in an employee-employer relationship with the NIH or the awardee institution.

It must be emphasized that the interpretation and implementation of the tax laws are the domain of the Internal Revenue Service and the courts. PHS takes no position on what the status may be for a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the law to their situations and for information on the proper steps to be taken regarding their tax obligations.

OTHER TRAINING COSTS

Tuition and fees, including self-only medical insurance, for the individual in training, are allowable trainee costs if such charges are required of all persons in a similar training status at the institution, without regard to their source of support. Family medical insurance coverage is not an appropriate charge to the NRSA research training grant. Tuition at the postdoctoral level is limited to that required for specific courses in support of the approved research training program.

Trainee travel, including attendance at scientific meetings that the institution determined to be necessary to the individual's research training, is an allowable trainee expense. In addition, support for travel to a research training experience away from the grantee institution may be permitted. Research training experiences away from the parent institution must be justified considering the type of opportunities for training available, how these opportunities differ from those offered at the parent institution, and the relationship of the proposed experience to the trainee's career stage and career goals. This type of research training requires prior approval from the NIH. Letters requesting such training may be submitted to the NIH awarding component at any time during the award period.

Institutional costs of up to \$1,500 per year per predoctoral trainee and up to \$2,500 per year per postdoctoral trainee may be requested to defray the costs of other research training related expenses, such as staff salaries, consultant costs, equipment, research supplies, and staff travel.

Under exceptional circumstances, which can include accommodating the disabilities of a trainee, it is possible to request institutional costs above the standard rate. These additional costs must be explained in detail and carefully justified in the application. Consultation with program staff in advance of such requests is strongly advised.

The institution may receive up to \$125 per month to offset the cost of tuition, fees, travel, supplies, and other expenses for each short-term, health-professional research training position.

An indirect cost allowance based on eight percent of total allowable direct costs (this excludes tuition), or actual indirect costs, whichever is less, may be requested. Applications from State and local government agencies may request full indirect cost reimbursement (see current PHS Grants Policy Statement).

REVIEW CRITERIA

Applications are evaluated for merit by NIH initial review groups based on the following criteria:

- o Past research training record of both the program and the designated preceptors as determined by the success of former trainees in establishing independent and productive research careers;
- o Past research training record in terms of the success of former trainees in obtaining individual research awards or fellowships and career awards for further development;
- o Objectives, design, and direction of the research training program;
- o Caliber of preceptors as researchers, including successful competition for research support;
- o The training environment, including the institutional commitment, the quality of the facilities, availability of appropriate courses, and the availability of research support;
- o Recruitment and selection plans for trainees, and the availability of high quality candidates;
- o The record of the research training program in retaining health-professional postdoctoral trainees for at least two years in research training or other research activities;
- o When appropriate, the concomitant research training of health-professional postdoctorates (i.e., individuals with

the M.D., D.O., D.D.S., etc.) with basic science postdoctorates (i.e., individuals with a Ph.D., etc.) or linkages with basic science departments.

Short-Term Research Training Positions: In addition to the above criteria, applications that request short-term research training positions will also be assessed using the following criteria:

- o The quality of the proposed short-term research training program including the commitment and availability of the participating faculty, the program design, the availability of research support, and the training environment;
- o Access to candidates for short-term research training and the ability to recruit high quality, short-term trainees from the applicant institution or some other health-professional school;
- o The characteristics of the research training program that might be expected to persuade short-term trainees to consider academic/research careers, particularly in clinical areas;
- o The success in attracting students back for multiple appointments;
- o The effects of the short-term training program on the quality of the regular research training program, including the appropriateness of the number of short-term positions, and the plan to integrate the short-term training program into the regular research training program;
- o The plan to follow former short-term trainees and assess the effect of such research training on their subsequent careers.

ADDITIONAL REVIEW CONSIDERATIONS

Minority Recruitment Plan: The NIH remains strongly committed to increasing the participation of individuals from underrepresented minority groups in biomedical and behavioral research.

As announced in 1989, all competing applications for institutional NRSA research training grants must include a specific plan to recruit minorities, and renewal applications also must include a report on the recruitment and retention record during the previous award period. If an application is received without a plan, or without a report on the previous award period, the application will be considered incomplete and may be returned to the applicant without review. Additional information on this requirement was published in the NIH Guide for Grants and Contracts, Volume 22, Number 25, July 16, 1993.

Competing renewal applications for research training grants must include a detailed account of experiences in recruiting individuals from underrepresented groups during the previous award period. Information on the types of recruitment strategies used and which have been successful and unsuccessful must be included. The report should provide information on the racial/ethnic distribution of: (a) students and/or postdoctorates in the department(s) relevant to the training grant, (b) individuals who applied for research training, (c) individuals who were offered admission, and (d) individuals who were appointed to the research training grant. For those trainees who were appointed to the grant, the report should include information about the duration of research training and whether those trainees have finished their training in good standing.

After the overall educational and technical merit of an application has been assessed, peer reviewers will examine and evaluate the record of the program in recruiting and retaining underrepresented minority trainees during the previous award period. The panel also will consider whether the experience in recruitment during the previous award period has been incorporated into the formulation of the recruitment plan for the next award period. The findings of the panel will be included in an administrative note to the summary statement. If the minority recruitment plan of the application is judged to be unacceptable, funding will be withheld until a revised plan that addresses the deficiencies is received. Staff within the awarding component, with guidance from the appropriate national advisory committee or council will determine whether amended plans and reports submitted after the initial review are acceptable.

Training in the Responsible Conduct of Research: Every predoctoral and postdoctoral NRSA trainee supported by an institutional research training grant must receive instruction in the responsible conduct of research. For more information on this provision, please consult a notice in the NIH Guide for Grants and Contracts, Volume 21, Number 43, November 27, 1992. Applications must include a description of a program to provide formal or informal instruction in scientific integrity or the responsible conduct of research. Applications without plans for instruction in the responsible conduct of research will be considered incomplete and may be returned to the applicant without review. Although the NIH does not establish specific curricula or formal requirements, all programs are encouraged strongly to consider instruction in the following areas: conflict of interest, responsible authorship, policies for handling misconduct, policies regarding the use of human and animal subjects, and data management. Plans must address the subject matter of the instruction, the format of the instruction, the degree of faculty participation, trainee attendance, and the frequency of instruction. The rationale for the proposed plan of instruction must be provided. Program reports on the type of instruction provided, topics covered, and other relevant information, such as attendance by trainees and faculty participation, must be included in future competing and noncompeting applications.

The NIH encourages institutions to provide instruction in the responsible conduct of research to all graduate students and postdoctorates in a training program or department, regardless of the source of support.

Initial review groups will assess plans on the basis of the appropriateness of topics, format, amount and nature of faculty participation, and the frequency and duration of instruction. The plan will be discussed after the overall determination of merit, so that the quality of the plan will not be a factor in the determination of the priority score. Plans will be judged as acceptable or unacceptable. The acceptability of the plan will be described in an administrative note. Regardless of the priority score, applications with unacceptable plans will not be funded until a revised, acceptable plan is provided by the applicant. The acceptability of the revised plan will be judged by staff within the awarding component at the NIH.

Following initial review, applications are also reviewed by the appropriate NIH Institute or Center Council, Board, or other advisory group. These advisory groups will consider, in addition to the assessment of the scientific and educational merit of the research training grant application, the initial review group's comments on the recruitment of individuals from underrepresented minority groups into the research training program and the plan for instruction in the responsible conduct of research.

REVIEW SCHEDULE

Application Receipt Date:	Jan 10	May 10	Sep 10
Initial Review Meeting:	Jun	Oct/Nov	Feb/Mar
Council/Board Meeting:	Sep/Oct	Jan/Feb	May/Jun
Earliest Start Date:	Dec 1	Apr 1	Jul 1

Many institutes review applications once per year. A table listing these institutes and the appropriate receipt dates is provided below.

Institute or Center	Application Receipt Date
National Institute of Child Health and Human Development	Jan 10
National Eye Institute	Jan 10
National Institute on Alcohol Abuse and Alcoholism	May 10
National Institute on Deafness and Other Communication Disorders	May 10
National Institute of Environmental Health Sciences	May 10
National Institute of Mental Health	May 10
National Institute of Neurological Disorders and Stroke	May 10
National Institute for Nursing Research	Sep 10
National Institute of Dental Research	Sep 10

Applicants are encouraged to contact appropriate Institute staff before preparing and submitting an application. Contacts are listed beginning on page 16.

APPLICATION PROCEDURES

Applicants must use the grant application form PHS 398 (rev. 9/91). This revision contains special instructions for Institutional National Research Service Awards.

Applicants who wish to include a request for short-term research training positions should identify short-term positions separately within the "Stipends" and "Training Related Expenses" categories on the budget page. Under "Stipends", short-term positions should be listed in the "Other" category. Tuition, fees, and insurance, and trainee travel, where necessary, are included in "Training Related Expenses." The description of the short-term research training program should be included in the application for the regular research training program, but should be separated from the description of the regular program within each section of the application. In addition to the information requested in the "Program Plan" section, the applicant should address the relationship of the proposed short-term program to the regular research training program and provide assurance that the short-term program will not detract from the regular program.

Applicants must observe the 25-page limit on the narrative section.

The form PHS 398 is available at institutional offices of sponsored research or their equivalent. If not available locally, call (301) 594-7248 or send a request, accompanied by a self-addressed mailing label to:

Office of Grants Information
Division of Research Grants
National Institutes of Health
Westwood Building, Room 449
Bethesda, MD 20892

FUNDING CRITERIA

Applications are selected for funding primarily on the basis of scientific and educational merit, but other factors are considered, such as: availability of funds, research program priorities, and balance among types of research training supported by the awarding component. The awarding NIH Institute will notify the applicant of the final action shortly after the advisory group meeting.

ADDITIONAL INFORMATION

For additional information, see the current document titled Guidelines for National Research Service Awards, Individual Awards - Institutional Grants usually available at the institution or contact the appropriate NIH staff person listed below.

AUTHORITY AND REGULATIONS

NRSA Institutional Research Training Grants are made under the authority of Section 487 of the Public Health Service Act as amended (42 USC 288). Title 42 of the Code of Federal Regulations, Part 66, is applicable to this program. This program is also described under the following numbers in the Catalog of Federal Domestic Assistance: 93.121, 93.172, 93.173, 93.272, 93.278, 93.282, 93.306, 93.361, 93.398, 93.821, 93.837-93.839, 93.846-93.849, 93.853-93.856, 93.859, 93.862-93.868, 93.871, 93.880, 93.894, and 93.929.

NIH STAFF CONTACTS

Applicants are strongly encouraged to contact the individuals designated below, in advance of preparing an application, for additional information concerning the areas of research, receipt dates, and other types of pre-application consultation.

NATIONAL INSTITUTE ON AGING (NIA)

Dr. Robin Barr

Telephone: (301) 496-9322

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

Dr. Ernestine Vanderveen, Division of Basic Research

Telephone: (301) 443-1273

Dr. Mary Dufour, Division of Biometry and Epidemiology

Telephone: (301) 443-4897

Ms. Frances Cotter, Division of Clinical and Prevention Research

Telephone: (301) 443-1207

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

Dr. Milton Hernandez

Telephone: (301) 496-7291

Dr. Leslye Johnson, Division of Microbiology and Infectious Diseases

Telephone: (301) 496-7051

Dr. Eugene Zimmerman, Division of Allergy, Immunology, and Transplantation

Telephone: (301) 496-8973

Ms. Nancy Brown, Division of AIDS

Telephone: (301) 496-0638

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)

Dr. Richard Lymn

Telephone: (301) 594-9959

NATIONAL CANCER INSTITUTE (NCI)

Dr. Vincent Cairoli

Telephone: (301) 496-8580

Dr. John Schneider

Telephone: (301) 496-8580

Dr. Andrew Vargosko

Telephone: (301) 496-8580

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)

Ms. Hildegard Topper

Telephone: (301) 496-0104

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS (NIDCD)

Dr. Daniel Sklare

Telephone: (301) 496-1804

NATIONAL INSTITUTE OF DENTAL RESEARCH (NIDR)

Dr. Thomas Valega

Telephone: (301) 594-7617

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

Dr. Walter Stolz

Telephone: (301) 594-7527

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

Dr. Timothy Condon

Telephone: (301) 443-6036

Dr. Charles Sharp, Division of Basic Research

Telephone: (301) 443-1887

Dr. Arthur Horton, Division of Clinical Research

Telephone: (301) 443-4060

Dr. Mario De La Rosa, Division of Epidemiology and Prevention Research

Telephone: (301) 443-6543

Dr. Heinz Sorer, Medications Development Division

Telephone: (301) 443-6270

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)
Dr. Michael Galvin
Telephone: (919) 541-7825

NATIONAL EYE INSTITUTE (NEI)
Dr. Maria Giovanni
Telephone: (301) 496-0484

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)
Dr. John Norvell
Telephone: (301) 594-7784

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)
Dr. Fann Harding, Division of Blood Diseases and Resources
Telephone: (301) 496-1817

Dr. John Fakunding, Division of Heart and Vascular Diseases
Telephone: (301) 496-1724

Ms. Mary Reilly, Division of Lung Diseases
Telephone: (301) 594-7466

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)
Dr. Harry Gwirtsman, Division of Clinical and Treatment Research
Telephone: (301) 443-3264

Dr. Kenneth Lutterman, Division of Epidemiology and Services Research
Telephone: (301) 443-3373

Dr. Stanley Schneider, Division of Neuroscience and Behavioral Science
Telephone: (301) 443-4347

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NINDS)
Mr. Edward Donohue
Telephone: (301) 496-4188

NATIONAL INSTITUTE FOR NURSING RESEARCH (NINR)
Dr. Ernest Marquez
Telephone: (301) 594-7865

Dr. Mary Lucas, Acute and Chronic Illnesses Branch
Telephone: (301) 594-7397

Dr. Sharlene Weiss, Health Promotion and Disease Prevention Branch
Telephone: (301) 594-7496

Dr. Patricia Moritz, Nursing Systems Branch
Telephone: (301) 594-7493

NATIONAL CENTER FOR HUMAN GENOME RESEARCH (NCHGR)
Dr. Bettie Graham
Telephone: (301) 496-7531

NATIONAL CENTER FOR RESEARCH RESOURCES (NCRR)
Dr. Harriet Gordon
Telephone: (301) 594-7945

OTHER NIH RESEARCH TRAINING PROGRAMS

The NIH provides other opportunities for training and career development for individuals interested in biomedical and behavioral careers. Some examples of these programs are:

- o NRSA Short-Term Institutional Research Training Grants
- o NRSA Individual Postdoctoral and Senior Fellowships
- o NIGMS Minority Predoctoral Fellowships
- o Minority Access to Research Careers (MARC) Program
- o Career Opportunities in Research (COR) Institutional Training Grants
- o Career Development (K) Awards
- o Research Supplements for Underrepresented Minorities
- o Research Supplements to Promote the Recruitment of Individuals with Disabilities into Biomedical Research Careers
- o Foreign-funded postdoctoral fellowships for research experiences abroad.

For a comprehensive list of programs that provide scientific training support at levels from high school to senior investigator, refer to "Research Training and Career Development Programs Supported by the National Institutes of Health. NIH Publication No. 92-2273." This booklet can be obtained by writing the Grants Information Office, National Institutes of Health, Westwood Building, Room 449, Bethesda, Maryland, 20892, telephone (301) 594-7248.

Agency for Health Care Policy and Research (AHCPR)

The AHCPR (formerly the National Center for Health Services Research and Health Care Technology Assessment) is a separate agency of the Public Health Service. AHCPR supports NRSA institutional training grants that allow predoctoral and postdoctoral trainees to gain experience in applying research methods to the systematic analysis and evaluation of health services. For information and application forms, contact the NRSA Project Officer, AHCPR Center for Research Dissemination and Liaison, 2101 East Jefferson Street, Suite 400, Rockville, MD 20852; telephone (301) 594-1362.

Health Resources and Services Administration (HRSA)

The HRSA is a separate agency within the Public Health Service. HRSA offers postdoctoral institutional research training grants for research training in primary medical care. These awards permit trainees to gain experience in applying research methods to the systematic analyses and evaluation of primary medical care. For information and application forms, contact the following offices at 5600 Fishers Lane, Rockville, Maryland 20857:

Grants Management Branch (T32)
Residency and Advanced Grants Section
Bureau of Health Professions, HRSA
Parklawn Building, Room 8C-26
Telephone: (301) 443-6002

Programmatic inquiries may be addressed to:

Division of Medicine, BHP/HRSA
Primary Care Medical Education Branch
Parklawn Building, Room 4C-04
Telephone: (301) 443-6820

NIH MIDWEST REGIONAL SEMINAR IN PROGRAM FUNDING AND GRANTS ADMINISTRATION

NIH GUIDE, Volume 23, Number 21, June 3, 1994

P.T. 42; K.W. 1014006

National Institutes of Health

A regional seminar covering topics related to program funding and grants administration at the National Institutes of Health (NIH) has been scheduled for July 21-22, 1994. The seminar, hosted by Northwestern University and held on its Evanston campus, is intended to attract faculty and research administrators from the midwest region of the United States, although those interested from other regions are also invited and welcome. Staff from small and minority colleges, for-profit research organizations, hospitals, universities, and medical centers are encouraged to attend.

This two-day seminar will have a dual focus of interest to both academic researchers, as well as new and senior research administrators. Discussions of current issues that affect NIH funding and grants administration will be featured to give conference participants a comprehensive view of NIH-sponsored research. There will be time available to network with fellow researchers and meet informally with NIH representatives to discuss topics of special interest.

Mr. Geoffrey Grant, Acting Director, NIH Office of Policy for Extramural Research Administration, and outstanding representatives from the Grants Policy Office, Division of Research Grants, and several awarding components of the NIH will be featured speakers.

SEMINAR LOGISTICS

Seminar Leader:
Geoffrey Grant, Acting Director
Office of Policy for Extramural Research Administration (OPERA)

Seminar Coordinator (NIH):
Joellen M. Harper, NIH Grants Policy Office, 301/496-5967

Seminar Coordinator (Northwestern):
Barbara Siegel, Office of Research and Sponsored Programs,
Northwestern University, 708/491-3003

Dates: Thursday and Friday, July 21-22, 1994

Location: Northwestern University, Evanston, Illinois

Cost of Workshop: \$100

REGISTRATION AND INQUIRIES

Advance registration is required by July 12, 1994. You are encouraged to register early, because conference space is limited to the first 300 registrants. For registration materials, send a FAX that provides your name, institution, address, telephone number, and anticipated number of registrants to Ms. Barbara Siegel, 708/491-4800. Individuals who previously asked to be placed on the mailing list for registration materials will receive them automatically. It is not necessary to request them again.

FUTURE SEMINARS

A SOUTHWEST SEMINAR will be hosted by the University of New Mexico in Albuquerque, New Mexico, November 17-18, 1994. To request registration materials, call 505/277-3942 or send a FAX that provides your name, institution, address, telephone number, and anticipated number of registrants to 505/277-8604. Registration materials will be finalized and mailed two to three months before the seminar.

At this time, the dates and locations for regional seminars to be held in 1995 have not been finalized. If you have any questions about hosting a regional seminar, contact Ms. Joellen Harper in the NIH Grants Policy Office on 301/496-5967.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

COMMUNITY CLINICAL ONCOLOGY PROGRAM

NIH GUIDE, Volume 23, Number 21, June 3, 1994

RFA AVAILABLE: CA-94-016

P.T. 34; K.W. 0715035, 0745027, 0745070, 0795003, 0403004

National Cancer Institute

Letter of Intent Receipt Date: July 1, 1994

Application Receipt Date: August 25, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites applications from domestic institutions for cooperative agreements to the Community Clinical Oncology Program (CCOP). New community and research base applicants and currently funded programs are invited to respond to this RFA as described below.

This issuance of the CCOP RFA seeks to build on the strength and demonstrated success of the CCOP over the past ten years by continuing the program to support community participation in cancer treatment and cancer prevention and control clinical trials through research bases (clinical cooperative groups and cancer centers supported by NCI) and utilizing the CCOP network for conducting NCI-assisted cancer prevention and control research.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Community Clinical Oncology Program, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

New applicants and currently funded programs are eligible as described below. Two types of grantees are eligible to apply: community programs and research bases. Community applicants may be a hospital, a clinic, a group of practicing physicians, a health maintenance organization (HMO) or a consortium of these. Community programs (CCOPs) will be required to enter patients onto NCI-approved treatment and cancer prevention and control clinical trials through the research base(s) with which each CCOP is affiliated.

Research base applicants must be either an NCI-funded clinical trials cooperative group or cancer center. Research bases will be required to provide clinical research treatment and cancer prevention and control protocols, monitor the quality research and follow CCOP accrual.

MECHANISM OF SUPPORT

Support of this program will be through the Cooperative Agreement (U10), an assistance mechanism in which substantial NCI programmatic involvement with the recipient during performance of the planned activity is anticipated, to assist awardees in the planning, direction, and execution of the proposed project. The total project period for applications submitted in response to this RFA may not exceed three years for new applicants and five years for applicants currently supported under this program. Currently supported applicants will be funded for three, four, or five years depending upon priority score/percentile, review committee recommendations, and programmatic considerations.

FUNDS AVAILABLE

It is anticipated that up to \$5.0 million in total costs per year for five years will be committed to specifically fund applications that are submitted in response to this RFA. Approximately two research base awards and up to 15 CCOP awards will be made. This level of support is dependent upon the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of NCI, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

Background

The CCOP was initiated in 1983 to bring the benefits of clinical research to cancer patients in their own communities by providing support for physicians to enter patients onto treatment research protocols. The second RFA, issued in 1986, expanded the focus to include cancer prevention and control research. In 1993, there were 48 programs in 27 states involving over 300 hospitals and over 2,900 physicians. Approximately 4,000 patients were entered onto treatment trials and 4,400 subjects on cancer prevention and control studies.

Cancer prevention and control research in the CCOPs is aimed at reducing cancer incidence, morbidity, and mortality through the identification, testing, and evaluation of interventions in controlled clinical trials. The 80 protocols activated to date cover the full spectrum of cancer prevention and control research, including chemoprevention and marker studies for future prevention interventions, smoking cessation studies, screening and early detection, and pain control and other symptom management interventions.

Goals and Scope

The CCOP initiative is designed to bring the advantages of state-of-the-art treatment and cancer prevention and control research to individuals in their own communities by having practicing physicians and their patients/subjects participate in NCI-approved treatment and cancer prevention and control clinical trials. The CCOP also provides a mechanism to increase the involvement of primary health care providers and other health care specialists in treatment and cancer prevention and control research and provides an opportunity for education and exchange of information on new technologies.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit by, June 24, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the principal investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NCI staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to Dr. Leslie G. Ford at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for cooperative agreements. These forms are available at most institutional offices of sponsored research; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/596-7248; and from the NCI program official listed under INQUIRIES.

A suggested format will be sent to all applicants requesting the RFA or submitting a letter of intent. Applicants are strongly encouraged to use the suggested format instructions in completing the PHS 398.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, exact, clear, and single-sided photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must also be sent to:

Ms. Toby Friedberg
Review Logistics Branch
National Cancer Institute
Executive Plaza North, Room 636
6130 Executive Boulevard
Rockville, MD 20852

Applications must be received by August 25, 1994. If an application is received after that date, it will be returned to the applicant.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by Division of Research Grants (DRG) staff for completeness and NCI staff for responsiveness. Incomplete or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NCI in accordance with the review criteria stated below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA. Applications judged to be competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the principal investigator/program director and the official signing for the applicant organization will be promptly notified. The second level of review will be provided by the National Cancer Advisory Board.

Review Criteria

Review Criteria for CCOP applicants include the ability to accrue a minimum of 50 credits per year to cancer prevention and control clinical trials and at least 50 credits to cancer treatment clinical trials. Review criteria for Research Bases include the ability to design appropriate treatment and/or prevention and control clinical trials. For both CCOPs and Research Bases the qualifications and experience of personnel and the stability and past performances of the functional unit applying will also be considered. The review group will critically examine submitted budgets and recommend an appropriate budget and period of support.

AWARD CRITERIA

The anticipated date of award is June 1, 1995. NCI program staff will take into account demographic and geographic distribution of applicants in the final funding selection process to assure inclusion of minority and underserved populations. Multiple CCOP applicants for funding who are competing for the same patient population will be considered, but all may not be awarded unless warranted by the population density.

INQUIRIES

Written and telephone requests for the RFA, inquiries concerning the objectives and scope of this RFA, or about whether or not specific proposed research are responsive are encouraged and may be directed to:

Leslie G. Ford, M.D.
Division of Cancer Prevention and Control
National Institute of Cancer
Executive Plaza North, Room 300-D
Bethesda, MD 20892
Telephone: (301) 496-8541

Direct inquiries regarding fiscal matters to:

Ms. Crystal Elliott
Grants Administration Branch
National Institute of Cancer
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800, Ext. 19

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 13.399, Cancer Control. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410 as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NIH GUIDE, Volume 23, Number 21, June 3, 1994

RFA AVAILABLE: CA-94-007

P.T. 34; K.W. 0715035, 0740020, 0710030, 0750025

National Cancer Institute

Letter of Intent Receipt Date: July 15, 1994

Application Receipt Date: September 20, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA). IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES", BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Developmental Therapeutics Program, Division of Cancer Treatment, National Cancer Institute (NCI), invites applications for cooperative agreements for the continuance of National Cooperative Natural Products Drug Discovery Groups (NCNPDDGs) for the discovery of new effective anticancer treatments from natural sources.

This RFA will support innovative, multi-disciplinary approaches to the discovery of new anticancer agents derived from natural sources. Each Group will be assembled by a Principal Investigator (PI) to form a multidisciplinary and multi-institutional consortium of skills needed to execute successfully the conceptualization, development, and preclinical investigation of the new, rationally based drug candidates. A multi-institutional approach involving academic, non-profit, and/or commercial/industrial institutions is envisaged because the existence of all of the creative talents in the required scientific disciplines will rarely be available in a single institution. The biological or molecular cancer targets for drug discovery and the sources and types of natural products to be investigated will be selected by the applicant groups. Although NCNPDDG awards will not support clinical trials, timely evaluation of drug candidates discovered by this mechanism is encouraged.

The present RFA is a reissuance of 89-CA-17 issued on September 14, 1989, with the same goals. The "Research Objectives" of the RFA require that an NCNPDDG has the capacity within itself to conceive, create and evaluate new approaches to discovery of natural products based drug candidates and to recommend the best candidates for development towards clinical trials. Subsequent studies required for development of new treatments to clinical trial (e.g., formulation development, classical toxicology, etc.) are beyond the scope of this RFA. Within this context, scientific approaches to the achievement of the RFA goals are broad, and are limited only by the creativity and the capability of the applicant group. The development of analogues of well-studied classes of anticancer agents is not responsive to this RFA.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," A PHS-led national activity for setting priority areas. This RFA, National Cooperative Natural Products Drug Discovery Groups, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, hospitals, laboratories, research institutes, units of State and local governments, and eligible units of the Federal government. Applications from women and minority investigators are encouraged.

MECHANISM OF SUPPORT

The administrative and funding instrument to be used for this program will be a cooperative agreement (U19), an "assistance" mechanism (rather than an "acquisition" mechanism) that differs from the research grant in that the Government component (NCI) awarding the Cooperative Agreement anticipates substantial scientific and/or programmatic involvement during performance of the award. Under the cooperative agreement, the NCI purpose is to support and/or stimulate the recipients activity by involvement in, and otherwise working jointly with, the award recipient in a partner role, but it is not to assume direction, prime responsibility, or a dominant role in the activity. Details of the responsibilities and the relationships of the awardee and the Government during the course of a cooperative agreement are found in the RFA under the section "Terms and Conditions of Award." The awardee will be responsible for the planning, direction, and execution of the proposed project, and interrelated activities. All applications must consist of at least three interrelated research projects. While no maximum number of projects is stipulated, it has been observed that awards containing more than five or six component projects are more difficult to manage.

The total project period for applications submitted in response to the present RFA may not exceed five years. The earliest anticipated award date is July 1, 1995. Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of awards may vary also.

Awards and level of support depend on receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the National Cancer Institute, awards pursuant to this RFA are contingent upon continuing availability of funds.

At this time, the NCI anticipates that there will be a renewed competition after five years. If the NCI does not

continue the program, awardees may submit grant applications through the usual investigator-initiated grants mechanisms.

FUNDS AVAILABLE

The NCI has set aside approximately \$4,000,000 in total costs for the initial year's funding. This level of support is dependent on the receipt of a sufficient number and diversity of applications of high scientific merit. Five to seven awards, which will include both new awards and competing continuation awards, are anticipated for project periods up to five years.

Awards are subject to a first year limit of \$900,000 total costs (direct plus indirect costs). Applications in excess of \$900,000 first year total costs will be returned without review.

RESEARCH OBJECTIVES

The goals of this RFA are to encourage the discovery and evaluation of new entities from natural sources for the treatment of cancer. Programs should utilize, to the extent possible, novel and innovative approaches to drug discovery based on recent advances in tumor biology and the molecular understanding of cancer. Programs appropriate to fulfillment of Group objectives could include, but are not limited to: discovery of natural products which selectively inhibit specific tumor types; products that may affect oncogene expression in tumors, signalling pathways for tumor growth, or the actions of hormones or growth factors on proliferation. Approaches to targets specifically present in tumor cells are encouraged as are applications that emphasize targets related to breast cancer and prostatic cancer, which are high priority research areas for the NCI.

The goals of the NATURAL PRODUCTS DRUG DISCOVERY GROUP PROGRAM are:

- o The search for, discovery, and isolation from natural sources of novel agents to treat cancer effectively and their evaluation in appropriately developed and/or selected preclinical models.
- o The development or use of preclinical models based on their ability to discriminate for antitumor activity and their ability to test the rationale for natural product selection and isolation.
- o The recommendation of promising new agents for development to clinical trial.
- o The design of preclinical studies that will facilitate subsequent clinical evaluation and correlation of preclinical and clinical data for validation of concept.

SPECIAL REQUIREMENTS

An NCNPDDG must be composed of a minimum of three inter-related projects (called laboratory programs in an NCNPDDG) led by independent investigators, and may consist of scientists from academic, non-profit research, and commercial organizations. A core component cannot be used to fulfill the requirement for three projects. Since the objective of the NCNPDDG program is the discovery of new and improved anticancer treatments, and active involvement by industry is facilitated by the existence of adequate patent coverage, it is essential that applicants provide plans to ensure such coverage.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 15, 1994, a letter of intent that includes a descriptive title of the proposed research, and if possible, names of members of the proposed Group and their institutions. The letter of intent is requested in order to provide an indication of the number and scope of applications to be reviewed. The letter of intent does not commit the sender to submit an application, nor is it a requirement for submission of an application. The letter of intent is to be sent directly to Dr. Matthew Suffness at the address indicated under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying. These forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 584-7248.

Additional instructions for the preparation of these multi-component applications are provided within the RFA and in the "Special Instructions to Applicants," which are available from the program staff listed under INQUIRIES. Recompeting groups must fully describe progress during the period of the previous award and describe the nature and extent of cooperation with the NCI. Applications not received by September 20, 1994 will be considered unresponsive and will be returned to the applicant without review.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the DRG and for responsiveness by the NCI. Incomplete applications will be returned to the applicant without further consideration. If NCI staff find that the application is not responsive to the RFA, it will be returned without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the Division of Extramural Activities, NCI in accordance with the review

criteria stated below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA. Applications judged to be competitive will be discussed and assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the principal investigator and the official signing for the applicant institution will be promptly notified.

INQUIRIES

Written, telephone, and FAX requests for this RFA and the opportunity to clarify questions from potential applicants are welcomed.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Matthew Suffness, Ph.D.
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 832
Bethesda, MD 20892
Telephone: (301) 496-8783
FAX: (301) 480-4883 or (301) 496-8333

Direct inquiries on budgets and grants policy issues to:

Barbara A. Fisher
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Suite 242
Bethesda, MD 20892
Telephone: (301) 496-7800 Ext. 229

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance number 93.395. Cancer Treatment Research. Awards will be made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Parts 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NATIONAL COOPERATIVE DRUG DISCOVERY GROUPS

NIH GUIDE, Volume 23, Number 21, June 3, 1994

RFA AVAILABLE: CA-94-008

P.T. 34; K.W. 0715035, 0755025, 0740020, 0755015

National Cancer Institute

Letter of Intent Receipt Date: July 15, 1994

Application Receipt Date: September 20, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA). IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Developmental Therapeutics Program, Division of Cancer Treatment, National Institute of Cancer (NCI), invites applications for the continuance of the National Cooperative Drug Discovery Group (NCDDG) Program. This RFA will support innovative, multidisciplinary approaches to the discovery of new anticancer agents and therapeutic strategies. Each group will be assembled by a principal investigator (PI) to form a consortium of skills needed to execute successfully the conceptualization, development, and preclinical investigation of new, rationally based treatments. A multi-institutional approach involving academic, nonprofit, and/or commercial/industrial institutions is envisioned because the existence of all the creative talents in the required scientific disciplines will rarely be available in a single institution. The biological or molecular targets of attack will be selected by the applying group. Either mechanism of action or disease-oriented approaches are being solicited. Although NCDDGs will not support clinical trials, a timely evaluation of products discovered by this mechanism is encouraged.

The present RFA is a reissuance of CA-91-19 issued on August 16, 1991, with the same goals. Applications are sought from both re-competing and new NCDDGs (also called Groups). The RESEARCH OBJECTIVES of this RFA require that an NCDDG has the capacity within itself to conceive, create, and evaluate new entities and strategies for the treatment of cancer. Subsequent studies required for development of new treatments and progression to clinical trial (e.g., formulation development, classical toxicology, etc.) are beyond the scope of this RFA. Applications with relevance to high priority diseases, such as breast and prostate cancer, are encouraged, but this RFA is not meant to exclude any approach or disease type. Scientific approaches to realization of Group goals are broad and limited only by the creativity and ability of the applicant. The development of analogs of established anticancer agents is not responsive to this RFA.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, National Cooperative Drug Discovery Groups, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications from minority and women investigators are encouraged.

MECHANISM OF SUPPORT

Awards will be made as cooperative agreements (U19), an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH scientific and/or programmatic involvement with the awardee is anticipated during performance of the activity. Under the cooperative agreement, the NCI purpose is to support and/or stimulate the recipient's activity by involvement in and otherwise working jointly with the award recipient in a partner role, but it is not to assume direction, prime responsibility, or a dominant role in the activity. Details of the responsibilities, relationships and governance of the study to be funded under cooperative agreement(s) are discussed in the RFA. The awardee will be responsible for the planning, direction, and execution of the proposed project and interrelated activities. All applications must consist of at least three interrelated projects. While no maximum number of projects is stipulated, it has been observed that when an award exceeds five component projects the program becomes more difficult to manage.

Each award will be made only to the Principal Investigator's institution. All Group activities will be coordinated through an Administrative Core located at the Principal Investigator's institution.

The total project period for applications submitted in response to the present RFA may not exceed five years. The earliest anticipated award date is July 1, 1995. Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the sizes of awards will vary also. At this time, the NCI anticipates that there will be a renewed competition of this program. If the NCI does not continue the program, awardees may submit grant applications through the usual investigator-initiated grants program.

FUNDS AVAILABLE

The NCI has set aside approximately \$4.0 million total costs for the first year of funding. This level of support is dependent on the receipt of a sufficient number and diversity of applications of high scientific merit. Four to six awards, which will include both new and competing continuation awards, are anticipated for project periods up to five years.

Awards are subject to a first year limit of \$900,000 in total costs (direct plus indirect costs). Budget requests should be carefully justified and commensurate with the needs of the project. Applications in excess of \$900,000 total cost will be returned without review.

RESEARCH OBJECTIVES

The goals of this RFA are to encourage the development of novel therapies and therapeutic strategies to improve survival of cancer patients and improve their quality of life. Approaches based on recent advances in molecular genetics and cancer cell biology, such as the role of oncogenes, tumor suppressor genes and cyclins in malignant transformation are especially encouraged. In addition to classical approaches of lead optimization in medicinal chemistry, drug design strategies based on receptor targets using computer modelling and other new technologies, such as combinatorial libraries, also are being solicited. Examples appropriate for the NCDDG program may include but are not limited to gene therapies, monoclonal antibodies, vaccines or the design of agents to interfere with transcription factors, signal transduction, cell adhesion factors, intracellular hormone receptors or other receptors, angiogenesis or other novel targets involved in the initiation/maintenance of the transformed state and for which a strong rationale can be provided.

The goals of the NATIONAL COOPERATIVE DRUG DISCOVERY GROUP program are:

- o The conceptualization, creation, and preclinical evaluation of new drugs and strategies designed to treat cancer effectively.
- o The recommendation of promising new treatment entities and/or strategies for development to clinical trial.
- o The conduct of biological, biochemical, and pharmacological studies that will permit enlightened clinical evaluation of agents or strategies identified by the NCDDG and that may provide information leading to the discovery of even more effective treatments.

SPECIAL REQUIREMENTS

An NCDDG must be composed of a minimum of three projects (called Laboratory Programs in an NCDDG) led by independent investigators with interrelated objectives, and may consist of scientists from academic, non-profit research, and commercial organizations. A core providing resources to two or more Laboratory Programs cannot be used toward fulfillment of the requirement for three projects. Since the discovery of new and improved anticancer treatments is the objective of this effort and active involvement by industrial laboratories is facilitated by adequate patent coverage, it is essential that applicants provide plans to assure such coverage. In addition, each PI and Program Leader must agree to NCI participation during performance of the award, and must provide a plan for development of a potential clinical trial candidate identified by NCDDG efforts, although advanced development and clinical trials are not supported by this mechanism.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by July 15, 1994 a letter of intent that includes a descriptive title of the proposed research, brief description of the proposed research, the name, address (including institution), and telephone number of the Principal Investigator, the identity of project leaders and titles of their projects, other key personnel, and their institutions, and number and title of this RFA. Although a letter of intent is not required, is not binding, and does not enter into the review of the application, the information that it contains allows NCI to estimate the potential workload for reviewers and to avoid possible conflict of interest in the review process. The letter of intent is to be sent to Dr. Mary K. Wolpert at the address listed under INQUIRIES below.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these cooperative agreements. This form is available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

Additional instructions for the preparation of these multi-component applications are available from program staff listed under INQUIRIES. Recompeting Groups must fully describe progress during the period of the previous award and describe the nature and extent of cooperation with the NCI. Applications not received by September 20, 1994 will be considered unresponsive and returned to the applicant without review.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by the NCI. Incomplete applications will be returned to the applicant without further consideration. If NCI staff find that the application is not responsive to the RFA, it will be returned without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NCI in accordance with the review criteria stated below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA. Applications judged to be competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the Principal Investigator/Program Director and the official signing for the applicant organization will be promptly notified.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct inquiries regarding programmatic issues, requests for the RFA and special instructions, and address the letter of intent to:

Mary K. Wolpert, Ph.D.
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Suite 832
Bethesda, MD 20892
Telephone: (301) 496-8783
FAX: (301) 496-8333 or (301) 402-0831

Direct inquiries regarding fiscal and administrative matters to:

Ms. Joan Metcalfe
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Suite 242
Bethesda, MD 20892
Telephone: (301) 496-7800, Ext. 28

AUTHORITY AND REGULATIONS

This program is described in the catalog of Federal Domestic Assistance No. 93.395, Cancer Treatment Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Parts 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

PRESCRIPTION DRUG USE, ABUSE, AND DIVERSION

NIH GUIDE, Volume 23, Number 21, June 3, 1994

PA NUMBER: PA-94-070

P.T. 34; K.W. 0404009, 0715129, 0740025

National Institute on Drug Abuse
National Institute of Mental Health

PURPOSE

The purpose of this program announcement is to encourage research on the use, misuse, abuse, and diversion of prescription psychoactive medications such as the opioids, stimulants, antipsychotics, antidepressants, anti-parkinsonism agents, anxiolytics, and sedative-hypnotics. Studies on the risk of addiction in patients being appropriately treated with psychoactive medications (particularly the analgesics, stimulants, anxiolytics, and sedative-hypnotics) for acute and chronic medical and psychiatric illnesses are particularly encouraged. Studies that assess the risk of abuse or addiction to prescribed psychoactive medications for known therapeutic indications in patients with a history of polydrug abuse are also encouraged.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Prescription Drug Use, Abuse, and Diversion, is primarily related to the priority area of alcohol and other drugs. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Women and minority investigators are encouraged to apply. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards.

MECHANISM OF SUPPORT

The mechanisms available for support of this program announcement are the research project grant (R01), small grant award (R03), and FIRST award (R29). Because the nature and scope of the research proposed in response to this program announcement may vary, it is anticipated that the size of an award will vary also.

RESEARCH OBJECTIVES

Background

This program announcement is a direct result of a prior request to the National Institute on Drug Abuse (NIDA) by the Office of National Drug Control Policy to evaluate the impact of prescription drug diversion control systems on medical practice and patient care. In response to this request, NIDA funded a review of available data and held two Technical Reviews to identify specific research areas. This review presented preliminary evidence that the treatment of patients with chronic and recurrent illnesses may be adversely affected by health professionals' fears that patients may abuse or become addicted to psychoactive medications. In addition, physicians may have concerns that regulatory agencies will discipline their prescribing practices and, as a result, undermedicate patients with legitimate need. (Reference, NIDA Research Monograph #131, 1993). While there is a need to prevent prescription drug abuse and diversion, this must be balanced with the need to have psychoactive medications available for legitimate medical and psychotherapeutic use.

Many anecdotes suggest that drug diversion control programs may adversely affect patient care. However, no systematic patient-based clinical research studies in which prescriptions are related to therapeutic need and risk of drug dependence are available to evaluate the merits of these reports. To evaluate validly and effectively any changes in prescribing patterns and the impact of comprehensive prescription drug regulatory mechanisms on patient care, research is needed that incorporates medical care data about individual patients and their use of psychoactive medications. Clinical studies are needed that take into account patients' histories, diagnoses and treatment, and the clinical appropriateness or inappropriateness of changes in prescribing practices. Surveys are also necessary to determine how attitudes, knowledge, and patterns of prescribing vary across categories of patients and prescribers in response to prescription drug control programs.

While existing data suggest that many patients benefit from long-term therapeutic use of psychoactive medications without evidence of abuse or addiction, no systematic studies exist either to identify those at risk of such consequences or to specify practice strategies best suited for at-risk patients. A range of research is needed to develop these strategies--from specifying the extent and nature of the problem (including health and social consequences) and identifying their determinants, to discovering effective clinical practices that identify those at risk and disseminating these practices to foster more appropriate care. Research on addiction risk factors associated with the chronic therapeutic use of analgesics, stimulants, and sedative-hypnotics for psychiatric and other medical illnesses is especially needed. Improved means of identifying who is at high risk of abusing or becoming addicted to prescribed psychoactive medications are needed to develop more effective prevention and intervention strategies.

Program Description

The primary purpose of this program announcement is to stimulate research on risk factors for abuse and addiction associated with the therapeutic use of analgesics, stimulants, anxiolytics, and sedative-hypnotics prescribed for psychiatric and other medical conditions (e.g., treatment-resistant depression, anxiety, panic disorder, attention-deficit hyperactivity disorder, obesity, malignant and non-malignant pain). Research is encouraged on the development and use of screening and assessment instruments to assess conveniently and reliably predictors of addiction in patients being treated with psychoactive medications for well-established medical and psychiatric indications. In addition, research on various clinical intervention strategies is also encouraged, particularly if the strategies present some potential for wide dissemination. Furthermore, studies to evaluate comprehensively the impact of prescription drug regulatory programs on medical practice and patient care are especially pertinent to the needs of this program. Applicants are advised to review existing information relevant to the Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care, published in the NIDA Research Monograph #131, 1993. Areas of research interest include, but are not limited to, the following:

- o Discovery of risk factors for abuse and addiction in patients with chronic or recurring psychiatric or medical conditions who take psychoactive medications chronically or recurrently. Obviously, in this group of patients, dependence upon medications needs to be distinguished from abuse of or addiction to them, if possible.
- o Clinical studies that assess the risk of abuse or addiction to any prescribed psychoactive medication for known therapeutic indications in patients with a history of polydrug abuse.
- o Clinical studies to determine effective clinical practices in the management of pain or anxiety in substance abusing patients.
- o Studies to develop better screening and assessment instruments for primary care settings to assess the need for and addictive risk of analgesics, stimulants, anxiolytics, and sedative-hypnotics in those patients being treated for medical or psychiatric complaints or conditions.
- o Surveys of the attitudes that primary care physicians have toward prescribing psychotropic medications, particularly in relation to attitudes about use of triplicate forms for prescribing controlled substances and in relation to attitudes about patients with drug abuse or psychiatric problems.
- o Detailed, comparative studies of the prescribing habits of various medical specialties. Since the populations that various specialties treat differ, these comparative studies should compare how case mix may influence the sensitivity and specificity of prescribing practices in relation to indications for prescribing controlled medications or for alternative treatments. Understanding the separate prescribing practices of internists, pediatricians, family practitioners, psychiatrists, anesthesiologists, neurologists, and oncologists is important.
- o Clinical research studies to determine the impact of diversion control mechanisms on medical practice and patient care, particularly prospective clinical outcome studies that incorporate prescriber and patient-level data from records of medical services, prescription drug utilization, data from health insurance claim files, and patient and practitioner interviews. Clinical studies are needed that take into account patients' histories, diagnoses, treatments and the clinical appropriateness or inappropriateness of changes in prescribing practices.
- o Epidemiologic and clinical studies to determine whether some patient populations may be under- or overmedicated or have difficulty obtaining adequate treatment with controlled substances as a result of prescription drug control programs. Models and instruments that have been developed to measure patients' satisfaction, quality of life, and functional status should be included in these studies.
- o Epidemiologic studies that explore the current prevalence of use of treatments for treatment-resistant depression, anxiety, panic disorder, attention-deficit hyperactivity disorder, obesity, and malignant and non-malignant pain. Alternative treatments include the use of non-controlled medications, as well as psychotherapeutically or physically based interventions. Studies that investigate any population-based feasibility of using effective and appropriate treatments that do not involve use of controlled substances are especially desirable.
- o Additional emphasis must be placed on including minorities and women of all ages in studies of diseases, disorders, and conditions that affect them specifically.
- o Policy studies to determine the impact of specific prescription drug regulatory mechanisms on medical practice and patient care.
- o Development of criteria or standards to be used in case identification of irresponsible prescribers and study of their use during case review by prescription drug diversion control systems (encompasses practice parameters and peer review).
- o Studies of the nature and magnitude of prescription drug diversion from both licit and illicit sources, the cost of processes involved in diversion control, reductions in diversion, and related outcomes resulting from regulatory changes.
- o Cost/benefit studies to determine how prescription drug regulatory programs affect the balance between preventing diversion and over-regulating medical prescribing practices.
- o Development and testing of epidemiological systems that utilize Federal and State data bases and are capable of effectively monitoring any diversion of pharmaceuticals. Systems that have the potential for generalized application in many jurisdictions and States, and for research purposes additional to monitoring drug diversion, are especially desirable.
- o Behaviorally based studies of physicians, pharmacists, nurses, and patients to determine the impact of comprehensive prescription drug regulatory mechanisms on health care practices, prescribing behaviors, medication dispensing, and delivered patient care. Studies of factors influencing prescribing decisions are needed to develop effective practitioner and patient education programs.

o Clinical and epidemiological studies of drug-abusing populations in and out of treatment and in various treatment settings (e.g., primary care, emergency rooms) pursuing the objectives: (1) to determine the nature, extent, and patterns of abuse of prescription drugs (including non-controlled drugs); (2) to find the sources of abused prescription drugs (including "doctor shopping"); (3) to understand the consequences of prescription drug use, misuse, and abuse to these individuals and their communities; (4) to assess the practical consequences of drug diversion to drug-abusing individuals and their communities; and (5) to estimate the incidence and prevalence of medical and psychiatric conditions in drug-abusing populations.

o Development and evaluation of innovative, skills-based, curricula in medical education that teaches how to prescribe medications and treatments appropriately and heightens professional awareness concerning patients likely to abuse psychoactive drugs.

o Development of interventions, ranging from one-to-one approaches to computerized strategies, to change patterns of misprescribing. Assessment of the stability of improved prescribing and its effects on patient outcomes would be integral to evaluating an intervention's utility.

The importance of a sound research plan and qualified research staff cannot be over-emphasized. It is recommended that investigators use the most rigorous methodology consistent with the purposes of the research. All applications must address issues of project feasibility, collaborative arrangements, study design and methodology, sampling procedures, instrumentation, data collection, quality control, and data analyses as appropriate. Since these kinds of research focus on areas of stigmatization and drug abuse, investigators should consider carefully how the confidentiality of patients and physicians will be protected during the course of the research.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 9, 1994 (FR 59 11146-11151), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the program staff or contact person listed below. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit. Application kits are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The title and number of the program announcement must be typed in item 2a of face page of the application.

FIRST applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The completed original application and five legible copies of the PHS 398 form must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary DHHS grant programs. Applications received under this program announcement will be assigned to an initial review group (IRG) in accordance with established PHS referral guidelines. The IRGs, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit in accordance with the standard NIH peer review procedures. Notification of the review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by an appropriate National Advisory Council, whose review may be based on policy considerations as well as scientific merit. Only applications recommended for further consideration by the Council may be considered for funding.

AWARD CRITERIA

Applications recommended for further consideration by an appropriate National Advisory Council will compete for available funds with all other approved applications assigned to the appropriate Institute. The following will be considered in making funding decisions: quality of the proposed project as determined by peer review; availability of funds; and institute program needs and balance.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding the programmatic issues focusing upon epidemiology or services research on addiction risk in patients being treated with analgesics, stimulants, anxiolytics and sedative-hypnotics for chronic medical and psychiatric illnesses and for studies that assess the risk of abuse or addiction to prescribed medications in patients with a history of drug abuse to:

Dorynne Czechowicz, M.D.
Division of Clinical Research
National Institute on Drug Abuse
5600 Fishers Lane, Room 10A-12
Rockville, MD 20857
Telephone: (301) 443-4877

Direct inquiries regarding programmatic issues focusing primarily upon epidemiology or services research regarding the psychiatric uses/abuses of anti-psychotic medications, antidepressant medications (including tricyclic antidepressants, monoamine oxidase inhibitors, selective serotonin reuptake inhibitors), buspirone and related medications, and medications used to treat pseudo-parkinsonism to:

Douglas Moul, M.D., M.P.H.
Division of Epidemiology and Services Research
National Institute of Mental Health
5600 Fishers Lane, Room 10C-09
Rockville, MD 20857
Telephone: (301) 443-3774

Direct inquiries regarding fiscal issues to:

Gary Fleming, J.D., M.A.
Grants Management Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 8A-54
Rockville, MD 20857
Telephone: (301) 443-6710

Diana S. Trunnell
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-08
Rockville, MD 20857
Telephone: (301) 443-3065

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.279. Awards are made under authorization of Section 301 of the Public Health Service Act (42 USC 241) and administered under PHS policies and Federal Regulations at Title 42 CFR 52 "Grants for Research Projects," Title 45 CFR Part 74 and 92, "Administration of Grants" and 45 CFR Part 46, "Protection of Human Subjects". Title 42 CFR Part 2, "Confidentiality of Alcohol and Drug Abuse Patient Records" may also be applicable to these awards. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Sections of the Code of Federal Regulations are available in booklet form from the U.S. Government Printing Office. Grants must be administered in accordance with the PHS Grants Policy Statement, (revised 10/90), which may be available from your office of sponsored research.

PA NUMBER: PA-94-071

P.T. 34; K.W. 0715133, 0765035, 0765014, 0790005, 1002004, 1002008

National Institute of Diabetes and Digestive and Kidney Diseases

PURPOSE

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) encourages research grant applications for support of studies on the identification, description and characterization of renal tubular epithelial ion transport mechanisms that may underlie pathophysiological states. The objective is to promote research at the molecular and cellular level to better understand aberrations in renal epithelial transport mechanisms that may lead to disease states.

The NIDDK, through its Division of Kidney, Urologic and Hematologic Diseases is the principal agency that supports fundamental and applied research directed at normal renal structure, function and regulation. These studies provide the basis for studies on the underlying mechanisms of kidney disease. This program includes studies utilizing whole kidney and/or the selected segments of the kidney or individual cells or any of their subcellular components as models. Those studies involving individual tubular segments, isolated cells and their component membranes have extended our knowledge of ion transport processes in the normal kidney, but still lacking is a comprehensive understanding of the many factors that govern body electrolyte balance and associated disease states. Nevertheless, the interactive play among receptors, modulatory proteins, phospholipid metabolites and second messengers is now becoming more clear in the modulation of ion transport, cytoskeletal organization, and growth and differentiation of the kidney. There are cellular and molecular biologic techniques that make it possible to identify and clone genes and proteins within renal epithelial cells responsible for anionic and cationic transport processes.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This PA will use the National Institutes of Health (NIH) individual research grant (R01) and FIRST (R29) award mechanisms. Responsibility for planning, direction, and execution of the proposed project will be solely that of the applicant. Because the nature and scope of the research proposal in response to this PA may vary, it is anticipated that the size of an award will vary also; however, the support of requests exceeding the NIDDK average grant size of \$160,000 direct cost for R01 grants would be unusual and require ample justification. FIRST (R29) awards are limited to \$350,000 over the five year period.

RESEARCH OBJECTIVES

Investigations are needed that will lead to functional connections between existing fundamental knowledge gained from physiological studies and, information yet to be obtained by directly addressing the pathophysiology in various renal tubular epithelial diseases. Examples of diseases with disorders of epithelial transport include: renal tubular acidosis, gout, cystinuria, nephrogenic diabetes insipidus, polycystic kidney disease and Fanconi and Bartters syndromes.

Responding applications should emphasize mechanisms rather than mere descriptions of processes. State-of-the-art biochemistry, and molecular and cellular biological techniques should be utilized in such investigations.

The following are examples of projects/topics that would be responsive, but are not meant to present the full range of possibilities:

- o The mechanisms underlying the involvement of specific ion solute and water transporters in hereditary kidney disease, such as polycystic kidney disease, cystinuria, nephrogenic diabetes insipidus or hereditary disorders of urinary proton, phosphorous, calcium and uric acid excretion.
- o The mechanisms underlying the involvement of specific ion solute and water transporters in acquired kidney disease, such as obstructive nephropathy, hyperaldosteronism, or drug-induced nephropathy.
- o The aberrant regulation by systemic hormones, intracellular second messengers, phospholipid metabolites, or ions in the expression and activities of different renal ion and solute transport systems.
- o Role and mechanism of action of analogs and/or antagonists of specific transport systems or hormones/growth factors/cytokines or their receptors in treatment of kidney disease.
- o Studies of immunohistochemistry and in situ hybridization in human biopsies of the pathophysiological basis of

abnormal urinary K⁺, Na⁺, Cl⁻, PO₄, and H₂O excretion.

- o Identification and functional significance of mutated genes whose expression is regulated by signal transduction through systemic hormones, growth factors, or other modulators in dysregulated endocrine or transport function.

- o The mechanisms underlying hypertrophy and upregulation of transport mechanisms in the renal response to partial loss of functioning nephrons.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 9, 1994 (FR 59 11146-11151) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

ANIMAL WELFARE CONSIDERATIONS

Investigators are encouraged to consider alternative methods and approaches in their research grant applications that do not require the use of whole animals, use alternative species such as nonmammals or invertebrates, reduce the number of animals required, and incorporate refinements to procedures that will result in the elimination or further minimization of pain and distress in animals.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the regular application deadlines for new research grant applications. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institute of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The title and number of this program announcement must be typed in Section 2a on the face page of the application. The earliest possible award dates will be approximately nine months after the respective receipt dates. Applications received too late for one review cycle will be held until the next receipt date.

Applications for FIRST awards (R29) must include at least three sealed letters of reference attached to the face page of the original application. First award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review. Applications will be received by the NIH Division of Research Grants (DRG) and referred to an appropriate study section for scientific and technical merit review. Institute assignment decisions will be governed by normal programmatic considerations as specified in the NIH referral guidelines. Following scientific-technical review, the applications will receive a second-level review by an appropriate national advisory council.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institute of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

The review criteria customarily employed by the NIH for research grant applications and FIRST awards will prevail. Following the initial scientific review, those applications recommended for further consideration will be evaluated by the appropriate National Advisory Council.

AWARD CRITERIA

Applications assigned to the National Institute of Diabetes and Digestive and Kidney Diseases will compete for available funds with all other approved applications assigned to the Institute. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written, email, and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

M. James Scherbenske, Ph.D.
Division of Kidney, Urologic and Hematologic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A-04A
Bethesda, MD 20816
Telephone: (301) 594-7522

Inquiries regarding fiscal matters may be directed to:

Helen Y. Ling
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 639
Bethesda, MD 20816

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.849. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

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June 10, 1994

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

THE PUBLIC HEALTH SERVICE (PHS) STRONGLY ENCOURAGES ALL GRANT RECIPIENTS TO PROVIDE A SMOKE-FREE WORKPLACE AND PROMOTE THE NON-USE OF ALL TOBACCO PRODUCTS. THIS IS CONSISTENT WITH THE PHS MISSION TO PROTECT AND ADVANCE THE PHYSICAL AND MENTAL HEALTH OF THE AMERICAN PEOPLE.

NOTICES

PROGRAM PROJECT GRANT APPLICATION GUIDELINES

NIH GUIDE, Volume 23, Number 22, June 10, 1994

P.T. 34; K.W. 0725000, 1014006

National Institute of Environmental Health Sciences

The National Institute of Environmental Health Sciences (NIEHS) announces the new NIEHS Program Project Grant Application Guidelines. These guidelines supersede all previous versions. The purpose of this notice is to highlight some important changes regarding program project applications to the NIEHS.

Applications Receipt Dates: Applications for program project grants are accepted by the NIEHS only on June 1 and October 1 of each year. Applications for program project grants will NOT be accepted by the NIEHS for the February 1 receipt date. This date is reserved for receipt of NIEHS center grant applications.

Site Visits: Although historically the NIEHS has utilized site visits as the primary means of initial review of program project applications, beginning with the June 1, 1994 receipt date, site visits will only be conducted in exceptional circumstances. The standard practice will be to conduct the initial review without site visits. Therefore, it is imperative that applications be very carefully and thoroughly prepared.

Submission of additional information prior to initial review: The new guidelines contain specific instructions for submission of additional information prior to the initial review of the application.

Supplemental Applications: Supplemental applications will be accepted only with prior concurrence of NIEHS program staff.

INQUIRIES

To obtain a copy of the Program Project Grant Application Guidelines and for specific questions about application procedures, contact:

Thorsten Fjellstedt, Ph.D.
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-0797
FAX: (919) 541-2843

HOW TO SECURE FUNDING FOR HIV/AIDS RESEARCH

NIH GUIDE, Volume 23, Number 22, June 10, 1994

P.T. 42, FF; K.W. 0715008

National Institute of Allergy and Infectious Diseases

A Minority Investigator Workshop, "How to Secure Funding for HIV/AIDS Research," sponsored by the Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID) and the Office of Research on Minority Health, NIH, will be held on September 28, 1994, from 8:30am to 8:00pm in Bethesda, Maryland. Presentations will include information about a future NIAID program targeted to underserved minority investigators in AIDS research and general grantsmanship information. Attendees may also apply for support to participate in the 1994 Annual Meeting of the Laboratory of Tumor Cell Biology, National Cancer Institute.

INQUIRIES

Additional information is available in the May 20, 1994 issue of Science 264:1221, 1994, and by contacting:

Ms. Maggie Robinson
Division of AIDS
National Institute of Allergy and Infectious Diseases
Solar Building, Room 2831
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 402-0756
FAX: (301) 480-5703
INTERNET: enhance@nih.gov

For investigators unable to the meeting, a summary will be available by contacting:

Janet Young
Division of AIDS
National Institute of Allergy and Infectious Diseases
Solar Building, Room 2828
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 402-0755

MEDICAL THERAPY IN BENIGN PROSTATIC HYPERPLASIA: FULL-SCALE TRIAL

NIH GUIDE, Volume 23, Number 22, June 10, 1994

RFA AVAILABLE: DK-94-018

P.T. 34; K.W. 0755015, 0715105, 0705075

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: August 2, 1994

Application Receipt Date: August 30, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Kidney, Urologic and Hematologic Diseases (DKUHD) of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), invites cooperative agreement applications from investigators to serve as a Clinical Center, and/or the Data Coordinating Center and/or the Diagnostic Center for the full-scale phase of the "Trial of Medical Therapy in Benign Prostatic Hyperplasia (BPH)."

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Medical Therapy of Benign Prostatic Hypertrophy: Full-Scale Trial, is related to the priority areas of diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Only U.S. organizations are eligible to apply. Domestic applications may not include international components. Applications may be submitted by for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications from minority and women investigators, minority institutions and institutions which may contribute substantial minority representation in the trial are encouraged.

The expertise appropriate for this research program for a Clinical Center includes a knowledge of the clinical and epidemiological aspects of urologic diseases as well as experience in the design and conduct of collaborative clinical trials and/or clinical investigations. Experience in recruitment and follow-up of a large number of patients with urologic diseases in clinical trials as well as clinical experience with a large number of patients with benign prostatic hyperplasia, is especially useful for Clinical Centers. Skills in management of multicenter clinical trials, establishing and maintaining a large data base, and analysis of complex data sets are appropriate for the Data Coordinating Center. For the Diagnostic Center, experience in collection, storage and pathological diagnosis of prostate biopsy specimens is important. The Diagnostic Center must also have the capabilities to measure prostate specific antigen and the hormones noted in the protocol.

An institution may apply to serve as a Clinical Center, the Data Coordinating Center, and the Diagnostic Center. However, a specific plan on how the independent operation (i.e., confidentiality of study-wide data) of each unit will be maintained is required. A separate application for each type of center will be required from an institution applying to serve as a Clinical Center, and/or the Data Coordinating Center and/or the Diagnostic Center.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC Program Director or Principal Investigator could be included with the application.

MECHANISM OF SUPPORT

The administrative and funding instrument to be used for this program will be a cooperative agreement (U01), which is an assistance mechanism rather than an acquisition mechanism in which substantial NIH scientific and/or programmatic involvement with the awardee is anticipated during performance of the activity. Under the cooperative agreement, the NIH purpose is to support and/or stimulate the recipient's activity by involvement in and otherwise working jointly with the award recipient in a partner role, but it is not to assume direction, prime responsibility, or a dominant role in the activity. Details of the responsibilities, relationships and governance of the study to be funded under cooperative agreement(s) are discussed later in this document under the section "Terms and Conditions of Award."

RESEARCH OBJECTIVES

The BPH Trial is a prospective, multicenter, randomized, placebo-controlled, double-masked clinical trial to determine if medical therapy (finasteride and/or doxazosin) delays or prevents the progression of benign prostatic hyperplasia (BPH). Patients will be randomly assigned to receive either finasteride, doxazosin, a combination of finasteride and doxazosin, or placebo. The primary outcome of the trial is time to progression of BPH as defined in the pilot study protocol. A sample of full-scale study participants will have prostate biopsies performed. The protocol for the ongoing BPH Pilot Study provides details on inclusion and exclusion criteria, baseline and follow-up procedures for participants,

and overall organization of the trial. The protocol and sample size requirements were developed by awardees under a cooperative agreement mechanism with NIDDK assistance. It is recommended that applicants obtain a copy of the protocol, available upon request from DKUHD, to assist them in preparing their response to this RFA.

Successful applicants for Clinical Centers will be eligible to apply for a second Request for Applications, "Basic Research Studies of Benign Prostatic Hyperplasia" which will be issued by February 28, 1995. Funding for this solicitation will be by means of supplements to cooperative agreements (U01).

LETTER OF INTENT

Prospective applicants are asked to submit, by August 2, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NIDDK staff to estimate the potential review workload and to avoid conflict of interest in the review.

A letter of intent is to be sent to:

Dr. Robert D. Hammond
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 605
Bethesda, MD 20892

APPLICATION PROCEDURES

Applications are to be submitted using form PHS 398 (rev. 9/91) available in the office of sponsored research at most academic or research institutions and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The RFA label available in the PHS 398 application form must be affixed to the bottom of the face page. Detailed instructions on submission procedures are described in the RFA.

REVIEW CONSIDERATIONS

Applications that are complete and responsive to the RFA will be evaluated by an appropriate peer review group convened by the NIDDK in accordance with the usual NIH peer review procedures. Following review, the application will be given a secondary review by the National Diabetes and Digestive and Kidney Diseases Advisory Council unless not recommended for further consideration by the initial review group. Applications that are incomplete or unresponsive to the RFA will be returned to the applicant.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Applicants are encouraged to request a copy of the pilot study protocol.

Direct requests for the RFA and inquiries regarding programmatic issues to:

John W. Kusek, Ph.D.
Division of Kidney, Urologic and Hematologic Diseases,
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A04
Bethesda, MD 20892
Telephone: (301) 594-7522
FAX: (301) 594-7501

Direct inquiries regarding fiscal matters to:

Trude H. McCain
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 653
Bethesda, MD 20892
Telephone: (301) 594-7543
FAX: (301) 594-7594

AUTHORITY AND REGULATIONS

This program is described in the catalog of Federal Domestic Assistance No. 93.849-Kidney, Urologic and Hematologic Diseases Research. Awards are made under the authority of the Public Health Service Act, Title IV Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.

NIH GUIDE, Volume 23, Number 22, June 10, 1994

RFA AVAILABLE: ES-94-008

P.T. 04; K.W. 0725000, 0710030

National Institute of Environmental Health Sciences

Letter of Intent Receipt Date: July 15, 1994

Application Receipt Date: September 8, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The overall intent of this National Institute of Environmental Health Sciences (NIEHS) program is to establish multi-disciplinary research programs supported by a core center (P30) that utilize state-of-the-art science. The focus is on environmentally related health problems of economically disadvantaged and/or underserved populations. The first step in this process is the current RFA, which requests developmental grant applications from institutions or consortia of institutions wishing to develop multi-disciplinary core center grants with this theme. It is important to note that the award of a developmental grant by the NIEHS does not imply a commitment to future funding of any resulting research or center grant applications. These must be submitted separately and will be evaluated on the basis of their own merit. The core center grant requires a research grant base of at least \$1,000,000 of outside peer reviewed awards related to environmental health problems, particularly focusing on economically disadvantaged and/or underserved populations. Therefore, it will require a substantial effort during the award period of the P20 grant to achieve the level of research support base necessary to qualify and compete successfully for a core center grant.

This RFA has one receipt date. However, the NIEHS intends to announce additional receipt dates for developmental grants periodically.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Developmental Grant: Environmental Health Sciences Centers, is related to the priority area of Environmental Health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applicants must have a minimum of \$500,000 in funded research related to environmental health sciences to be eligible for this solicitation. Applications may be submitted by domestic for-profit and non-profit organizations, public and private. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) exploratory grant (P20). The maximum requested amount of each application may not exceed \$175,000 direct cost per year. The total project period may not exceed three years.

FUNDS AVAILABLE

The level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NIEHS, awards pursuant to this RFA are contingent upon the availability of funds for this purpose. The earliest possible date is April 1, 1995. Funding beyond the first and subsequent years of the award will be contingent upon satisfactory progress during the preceding year and upon availability of funds. It is estimated that approximately one to three awards will be made.

RESEARCH OBJECTIVES

The primary purpose of the NIEHS developmental grant will be to provide support for a group of investigators to develop interdisciplinary collaborations and strategies, to obtain preliminary results to demonstrate feasibility, and to develop a research program addressing the above-cited PURPOSE of the NIEHS in this RFA. The resulting program will then be used as the basis for an application for other NIEHS project grants and ultimately a core center grant (P30). The objectives for an NIEHS developmental grant may include, but are not limited to:

- o Preliminary or feasibility studies to gather sufficient data to demonstrate the potential of an idea or the validity of an approach, to acquire or demonstrate technical competence, or to evaluate other technical factors involved in the development of a project that addresses the goal of this initiative;
- o Recruitment of new investigators whose expertise would strengthen the overall research project base in a subsequent core center grant application;
- o Inter- or intra-institutional planning to develop research strategies, including the establishment of a timetable or milestones, for the development of grant applications that are prerequisite for the NIEHS Core Center grant application.

SPECIAL REQUIREMENTS

In addition to yearly staff review through progress reports, the directors of developmental grants will be asked to attend the periodic meetings of the Environmental Health Sciences Center Directors for discussions of progress towards establishing the interdisciplinary effort needed to apply for an NIEHS center.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by July 15, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIEHS staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Dr. Ethel Jackson
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, 104 Alexander Drive, MD 17-09
Research Triangle Park, NC 27709
Telephone: (919) 541-7826

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev.9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248.

Applications must be received at the NIH by September 8, 1994. The RFA label available in the PHS 398 application form must be affixed to the bottom of the face page of the application. In addition, the RFA title and number must be typed on line 2a of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must also be sent to:

Dr. Ethel Jackson
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, 104 Alexander Drive, MD 17-09
Research Triangle Park, NC 27709
Telephone: (919) 541-7826

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by the NIEHS. Incomplete applications will be returned to the applicant without further consideration. If staff find that the application is not responsive to the RFA, it will be returned without further consideration. Site visits as part of the initial review of applications are not planned. Therefore, it is imperative that the application be complete and stand on its own merits.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIEHS in accordance with the review criteria stated below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA. Applications judged to be competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the principal investigator/program director and the official signing for the applicant organization will be promptly notified.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. However, potential applicants are expected to have reviewed the material in the RFA before contacting the NIEHS.

To receive a copy of the RFA, contact the NIEHS either by FAX at 919-541-2843 or Voice Mail at 919-541-3319. Be sure to include your complete mailing address and phone number.

Direct mail inquiries to receive a copy of the RFA and inquiries regarding programmatic issues to:

Donald I. McRee, Ph.D.
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, 104 Alexander Drive, MD 3-02
Research Triangle Park, NC 27709

Direct inquiries regarding fiscal matters to:

Mr. David L. Mineo
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, 104 Alexander Dr., MD 2-01
Research Triangle Park, NC 27709
Telephone: (919) 541-1373

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.894. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 43 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

DATA ACQUISITION AND ANALYSIS CENTER FOR BEHAVIORAL RESEARCH

NIH GUIDE, Volume 23, Number 22, June 10, 1994

RFA AVAILABLE: HD-95-004

P.T. 34; K.W. 0404000, 0755018

National Institute of Child Health and Human Development

Application Receipt Date: September 13, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Child Health and Human Development (NICHD) invites applications for a cooperative agreement to participate as the Data Acquisition and Analysis Center (DAAC) in support of planning and conducting research on the contexts of development and developmental outcomes of children who are participating in Phase II of the NICHD Study of Early Child Care (SECC). The second phase of the study will start in the beginning of 1995 and will be continued for a period of five years.

The Data Acquisition and Analysis Center (DAAC) for Phase II of the NICHD SECC will provide leadership and consultation in the execution, close-out and analysis of the Phase II study. It will ensure that the results of the study and its subprotocols are of the highest scientific integrity and meet rigorous statistical standards. The DAAC will be functionally independent of all research sites, although it could be physically located in one of the participating institutions.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Data Acquisition and Analysis Center for Behavioral Research, is related to the health of children and their families. It is also related to the Minority Health Initiative of the National Institutes of Health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, units of State and local governments, and eligible agencies of the Federal government. Applications from minority and women investigators are encouraged. Evidence of existing research capabilities for multi-site studies must be demonstrated.

MECHANISM OF SUPPORT

The mechanism used to support this research is the Cooperative Agreement (U01), in which substantial NIH scientific and/or programmatic involvement with the awardee is anticipated during the performance of the activity. Under the cooperative agreement, the NIH purpose is to support and/or stimulate the recipient's activity by NICHD staff's involvement in the research and by NICHD staff working jointly with the award recipient in a partner role. It is, however, understood that NICHD staff is not to assume direction, prime responsibility, or a dominant role in the research activity. Specifically, in the case of the SECC, the study will continue to be conducted as a collaboration among awardees at the data collection sites, the awardee at the DAAC and the NICHD scientific program staff. Details of the responsibilities, relationships and governance of the DAAC to be funded under the cooperative agreement are discussed in the RFA under the section "Terms and Conditions of Award."

The total requested project period for an application submitted in response to the present RFA may not exceed five years. The anticipated start date is April 1995. At this time, the NICHD has not determined whether or how this solicitation will be continued beyond the present RFA.

FUNDS AVAILABLE

It is anticipated that one award will be made for a data acquisition and analysis center for Phase II of the NICHD SECC. The estimated total cost for the first year is \$750,000. Although this program is provided for in the financial plans of NICHD, the award of grants pursuant to this RFA is contingent on the scientific and technical merit of the application and on the availability of funds for this purpose.

RESEARCH OBJECTIVES

Research Goals and Scope

The specific goal of the requested follow-up is to continue to investigate the contexts of development and their impact on the same developmental domains investigated in the first phase of the study (the study of the children from one through 36 months of age). Therefore, applicants for the DAAC need to present a plan for data acquisition, monitoring, reduction and analysis for a follow-up study that is comprehensive, describing the environments of child development and tapping the social, emotional, cognitive, linguistic, academic and health aspects of the development of children. The applicants will need to demonstrate expertise in handling all aspects of (a) observational and test data collection at two time periods between the ages of three and seven and (b) telephone and/or mail data collection in the periods between the face-to-face data collection periods.

In addition, applicants need to describe a plan for creating a data set that is compatible with that developed by the DAAC involved in Phase I of the study. This is important because the data sets from Phase I and Phase II of the study will need to be merged to allow analyses across the different age periods.

SPECIAL REQUIREMENTS

The DAAC must have expertise in research design as well as in statistical methods appropriate for multi-site longitudinal research designed primarily by developmental psychologists using questionnaires, interviews, observations and tests as methods of data collection. The DAAC will serve as a centralized information management system for collecting, editing, storing and analyzing data. It will be responsible for ensuring data integrity, accuracy, and accessibility to the investigators of the study. It will be responsible for the timely production of operation manuals detailing the study. It will maintain strict independence from the other sites participating in the cooperative agreement and will compile, as needed, progress reports of ongoing components of the study. Examples of additional functions of the DAAC are spelled out in the RFA.

STUDY POPULATION

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

APPLICATION PROCEDURES

All applicants must document their ability to meet or exceed the minimum requirements as set out in the "SPECIAL REQUIREMENTS" section of the RFA.

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for the award. This form is available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20982, telephone (301) 584-7248; and from the NIH Scientific Project Coordinator listed under INQUIRIES. Applications must be received by September 15, 1994. Applications received after that date will be returned to the applicants without review.

REVIEW CONSIDERATIONS

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NICHD in accordance with the review criteria stated below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA. Applications judged to be competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the Principal Investigator and the official signing for the applicant organization will be notified.

In addition to standard criteria used in NIH peer review for the evaluation of scientific and technical merit, special additional evaluation criteria for the application are spelled out in the RFA.

AWARD CRITERIA

The award date is April 1, 1995. Applications recommended by the NICHD Advisory Council will be considered for award based upon (a) scientific and technical merit; (b) sufficient compatibility of features that promise to enhance collaboration; and (c) availability of funds.

Application Receipt Date: September 13, 1994
Review by NICHD Advisory Council: January 31, 1995
Anticipated Award Date: April 1, 1995

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Sarah L. Friedman, Ph.D.
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
Building 61E, Room 4B05
Bethesda, MD 20892
Telephone: (301) 496-6591
FAX: (301) 402-2085
Bitnet: SF2@NIHCU

Direct inquiries regarding fiscal matters to:

Mary Ellen Colvin
Office Of Grants and Contracts
National Institute of Child Health and Human Development
Building 61E, Room 8A17
Bethesda, MD 20892
Telephone: (301) 496-1303
FAX: (301) 402-0915
Bitnet: QMI@NIHCU

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.865. Awards are made under the authorization of the Public Health Services Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

COLLABORATIVE CANCER PREVENTION RESEARCH UNITS

NIH GUIDE, Volume 23, Number 22, June 10, 1994

RFA AVAILABLE: CA-94-009

P.T. 34; K.W. 0715035, 0745027, 0745035

National Cancer Institute

Letter of Intent Receipt Date: August 11, 1994
Application Receipt Date: October 13, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Cancer Control Science Program within the Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI), seeks to stimulate the establishment of programs in primary and secondary cancer prevention, health promotion and prevention services research through the award of grants involving project-specific collaborations.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Collaborative Cancer Prevention Research Unit (CCPRU), is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-004731) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, non-profit and for-profit organizations, public and private entities such as universities, colleges, hospitals, laboratories, units of state or local governments, and eligible agencies of the federal government. Applications from minority and women investigators are encouraged. Foreign institutions are not eligible to apply for First Independent Research Support and Transition (FIRST) (R29) awards.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) Research grant mechanism (R01), and the First Independent Research Support and Transition (FIRST) Award grant mechanism (R29). The CCPRU must consist of a minimum of two independent applications. An CCPRU package can consist of a combination of R01s and R29s, or R01s only, but may not consist of solely R29 applications. The total project period for R01 applications submitted in response to the present RFA may not exceed four years. R29 awards must be for five years. The anticipated award date is July 1, 1995. This is a one-time solicitation. Future unsolicited competing continuation applications will compete with the investigator initiated applications and will be reviewed according to customary NIH peer review procedures.

FUNDS AVAILABLE

Approximately \$3 million, per year, in total costs for four years will be committed to specifically fund applications which are submitted in response to this RFA. It is anticipated that up to five (a combination of approximately 10 individual R01 and R29 projects) CCPRU awards will be made. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

DCPC supports research with an emphasis on studies to identify, evaluate, and implement techniques and approaches for primary and secondary prevention of cancer. Those studies may include specific cancers such as breast or prostate or more general areas of prevention research such as cancer prevention and screening among special populations, chemoprevention, tobacco prevention among children and adolescents, diet and nutrition, and early detection.

The CCPRU should focus on problem- or program-oriented cancer prevention research studies, involve multidisciplinary participation, and, for Phase IV and V studies, need to have access to defined populations in order to measure the population impact of any cancer control activities. The CCPRU concept envisions a multidisciplinary environment of scientist interacting closely in the research program. These can include new as well as experienced investigators in relevant fields and disciplines, such as disease prevention and control, medicine, public health, health education, health promotion, epidemiology, nutrition sciences, environmental and occupational health, health policy and economics, health services research, behavioral and social sciences, community organization, communications, and biostatistics.

Linkages between laboratory research and applied cancer prevention and control research are encouraged, i.e., laboratory research in support of these prevention studies. Basic laboratory research without this linkage will be deemed non-responsive to the RFA.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by August 11, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other collaborating personnel and participating institutions, and the number and title of this RFA in response to which the application may be submitted.

The letter of intent is to be sent to Dr. Sherry Mills at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248. Applications must be received by October 13, 1994.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by the NCI. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NCI in accordance with the review criteria stated below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Sherry Mills, M.D., M.P.H.
Division of Cancer Prevention and Control
National Cancer Institute
Executive Plaza North, Room 320
Bethesda, MD 20892
Telephone: (301) 496-8520

Direct inquiries regarding fiscal matters to:

Marian F. Focke
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Suite 243
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 246

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No 93.399. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

PATHOPHYSIOLOGY OF ALCOHOL AND DRUG-INDUCED PANCREATITIS

NIH GUIDE, Volume 23, Number 22, June 10, 1994

RFA AVAILABLE: DK-94-022

P.T. 34; K.W. 0715085, 0765035, 0404003, 0715006

National Institute of Diabetes and Digestive and Kidney Diseases
National Institute on Alcohol Abuse and Alcoholism

Letter of Intent Receipt Date: September 22, 1994
Application Receipt Date: October 20, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Digestive Diseases and Nutrition of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) wish to encourage applications on the above subject. This includes basic and clinical studies into the pathophysiology of alcohol and drug induced pancreatitis.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Pathophysiology of Alcohol and Drug-Induced Pancreatitis, is related to the priority area of diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Minority individuals and women are encouraged to submit as principal investigators.

MECHANISM OF SUPPORT

Support of this program will be through the NIH research project grant (R01), and the FIRST (R29) award. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the PHS Grants Policy Statement.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and, R01 applications will be reviewed by a DRG study section under the normal peer review process. The total project period for each application for an R01 grant submitted in response to this RFA may not exceed five years (three years may be requested for foreign awards). The earliest possible award date will be July 1, 1995.

FUNDS AVAILABLE

For FY 1995, \$1.5 million will be committed to fund applications submitted in response to this RFA. It is anticipated that five to eight awards will be made; one to two by NIAAA and four to six by NIDDK. However, this funding level is dependent upon the receipt of a sufficient number of applications of high scientific merit. Applications must limit

their initial budget period request to not more than \$150,000 in direct costs. R29 Award applications must adhere to the R29 guidelines for budget and period of award. Although this program is provided for in the financial plans of the NIDDK and NIAAA, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The overall goal of this initiative is to encourage experienced and new investigators to pursue basic and clinical investigations into the pathophysiology of alcohol and drug-induced pancreatitis. Although there has been considerable research into the physiology of the pancreatic acinar cell as well as the function and diseases of the pancreatic duct cell, continued research efforts need to be focused on pancreatitis with a particular emphasis on alcohol and other medications and toxins as etiological factors. At present, it is still unclear how alcohol abuse or drugs induce the auto-destructive tissue necrosis observed in acute pancreatitis. It has been postulated that the initial insult produces damage to the acinar cell or promotes ductal obstruction thereby releasing auto-destructive enzymes and initiating the pancreatic pathological sequelae. More recent investigations have suggested that inhibition of mitochondrial function by drugs may lead to cell injury and release of destructive enzymes. A number of drugs are considered to cause pancreatitis. They include thiazide diuretics, azathioprine, 6-mercaptopurine, dideoxyinosine, 1-2' deoxy- 2' fluoro-1-B-D arabinofuranosyl-5 iodo-uracil (FIAU) and valproate. Elevated estrogen levels or the administration of corticosteroids or estrogens aggravate hypertriglyceridemia, which can precipitate pancreatitis.

Chronic pancreatitis, characterized by recurrent or persistent pain, is characterized by focal inflammation and fibrosis. Pancreatic ducts may be dilated and obstructed by intraductal plugs. Exocrine or endocrine insufficiency may also be observed. Alcohol consumption is a complicating factor in at least half of the reported cases of chronic pancreatitis. Whether or not alcohol injures pancreatic tissue directly through intestinal hormones (cholecystokinin and secretin) and or through mechanisms involving pancreatic enzymes needs clarification.

Cytokines and or growth factors, such as tumor necrosis factor, may be involved in the pathogenesis of alcohol-related pancreatitis since this factor is elevated in bile-induced pancreatitis in rats and in patients with alcoholic hepatitis. In addition, oxygen-derived free radicals have been implicated in the development of pancreatitis in mice. Whether or not alcohol-induced free radical development is causally related to pancreatitis needs investigation.

Increased pancreatic synthesis of fatty acid ethyl esters (FAEEs) is associated with chronic alcohol feeding. FAEEs have also been shown to increase the fragility of isolated pancreatic lysosomes thereby releasing destructive, lysosomal enzymes. Thus, mechanisms that elucidate FAEEs contribution to the development of alcohol-related pancreatitis are warranted.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by September 22, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of the subsequent application, the information that it contains is helpful in planning for the review of applications. It allows NIDDK and NIAAA staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Chief, Review Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 605
Bethesda, MD 20892
Telephone: (301) 496-7083
FAX: (301) 594-7503

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) available in the offices of sponsored research of most academic or research institutions and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The RFA label available in the PHS 398 application form must be affixed to the bottom of the face page. Detailed instructions on submission procedures are described in the RFA.

REVIEW CONSIDERATIONS

Applications that are complete and responsive to the RFA will be evaluated by an appropriate peer review group convened by the NIDDK and NIAAA in accordance with the usual NIH peer review procedures. Following review, the applications will be given a secondary review by the NIDDK and NIAAA Advisory Councils unless not recommended for further consideration by the initial review group. Applications that are incomplete or unresponsive to the RFA will be returned to the applicant or held until the next regular receipt date and reviewed by the Division of Research Grants.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Inquiries regarding programmatic issues may be directed to:

Thomas F. Kresina, Ph.D.
Division of Digestive Diseases and Nutrition
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A-17
Bethesda, MD 20892
Telephone: (301) 594-7578

Vishnudutt Purohit, Ph.D.
Division of Basic Research
National Institute on Alcohol Abuse and Alcoholism
6000 Executive Boulevard, Suite 402
Rockville, MD 20892-7003
Telephone: (301) 443-4224

Inquiries regarding fiscal matters may be directed to:

Mrs. Thelma Jones
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 649
Bethesda, MD 20892
Telephone: (301) 594-7543

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.848. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

PROGRAM PROJECTS IN NUTRITION AND BASIC BIOLOGY RESEARCH FOR CANCER PREVENTION

NIH GUIDE, Volume 23, Number 22, June 10, 1994

RFA AVAILABLE: CA-94-018

P.T. 34; K.W. 0715035, 0710095, 0745027

National Cancer Institute

Letter of Intent Receipt Date: July 25, 1994
Application Receipt Date: November 18, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Cancer Prevention and Control and the Division of Cancer Etiology, National Cancer Institute (NCI), invite Program Project Grants for multidisciplinary nutrition and basic biology research relevant to the prevention of cancer. Specifically, they seek to encourage application of the techniques of molecular biology and molecular genetics to address questions about the fundamental role of nutrition in the initiation, promotion, progression, and prevention of cancer and the use of that knowledge to develop dietary interventions for the prevention of cancer, with a special emphasis on breast cancer, prostate cancer, and cancer in women and minorities.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Program Projects in Nutrition and Basic Biology Research for Cancer Prevention, is related to the priority areas of cancer and nutrition. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Domestic non-profit and for-profit organizations and institutions, public and private, are eligible to apply. Applications may be submitted from a single institution or may include arrangements with multiple institutions if appropriate. Applications from or involving minority institutions and from minority and women investigators are encouraged. Foreign institutions are not eligible.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) Program Project Grant (P01). The total project period for applications must not exceed four years. Because the nature and scope of the research proposed in response to this RFA may vary, the size of awards may vary also. This is a one-time solicitation.

FUNDS AVAILABLE

Up to \$4 million in total costs per year for up to four years will be committed specifically to fund applications that are submitted in response to this RFA. It is anticipated that three to four awards will be made. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The multidisciplinary studies encouraged by this RFA will employ innovative approaches to examine fundamental effects of nutrients and other food constituents on initiation, promotion, progression, and prevention of cancer, as well as individual variability in response, to develop more effective nutrition interventions for prevention of cancer, especially breast and prostate cancer and other cancers affecting women and minorities. Illustrative, but not exhaustive, examples of research areas relevant to nutrition and basic biology research for the prevention of cancer are as follows:

- o Evaluate nutrient-genome interactions in carcinogenesis and anticarcinogenesis, e.g., nutrient effects on DNA repair or modulation of gene expression.
- o Examine the potential for nutrients or other dietary constituents to influence the activation of oncogenes or inactivation of tumor suppressor genes.
- o Study nutrient influences on differentiation and on signals induced by physiological or chemical differentiation in various tissues.
- o Evaluate nutrient effects on growth factors for cellular transformation, including the ability to block or prevent the interaction of growth factors with receptors.
- o Examine nutrient-carcinogen-promoter interactions, including cellular defense mechanisms against environmental carcinogens/promoters that may be regulated by dietary factors.
- o Elucidate mechanisms and controls of nutrient transport to target sites in various tissues.
- o Quantify dose-response relationships for nutrients, nutrient derivatives, and other bioactive dietary constituents as part of the evaluation of their absorption, metabolism, and distribution in target tissues and their effects on molecular and cellular events.
- o Identify biomarkers indicative of early cellular transformation that may be monitored in nutrition epidemiologic studies and modulated in dietary intervention trials.
- o Identify biomarkers that will provide improved assessment of dietary intake and/or nutritional status for use in nutrition epidemiologic studies and dietary intervention trials.
- o Characterize the nature, extent, and causes of individual variability in cancer risk and in responses to dietary constituents.
- o Develop dietary intervention strategies to modulate expression of genetically determined cancer risk, including risk resulting from loss of response to natural regulators of proliferation and/or risk resulting from blocked expression of differentiation (maturation) programs.
- o Conduct small-scale clinical/metabolic intervention studies to test dietary modifications with potential for cancer prevention developed on the basis of knowledge of nutrient-genomic interactions.

SPECIAL REQUIREMENTS

The Program Project Grant is intended for the support of a multidisciplinary research program with a focused theme. To be responsive to this RFA, a Program Project must include basic research efforts and at least one component project involving studies of human subjects or human tissues, but should be no larger than necessary to achieve the desired collaboration among participating basic biology and nutrition investigators. It may also contain one or more core component(s). Other required applicant information and special instructions for preparation of Program Project Grant applications are included in the full text of this RFA, which is available on request from the NCI program administrators listed under INQUIRIES.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by July 25, 1994, a letter of intent that includes the names of the principal investigator and principal collaborators; a descriptive title of the potential application and a list of titles for the

anticipated components of the P01; identification of the organization(s) involved; and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it is requested in order to provide an indication of the number and scope of applications to be reviewed and to allow NCI staff to avoid conflict of interest. The letter of intent is to be sent to:

Ms. Toby Friedberg
Division of Extramural Activities
National Cancer Institute/NIH
Executive Plaza North, Room 636
Bethesda, MD 20892
Telephone: (301) 496-3428
FAX: (301) 402-0275

APPLICATION PROCEDURES

Applications must be received by November, 18, 1994. The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248; and from the NCI program administrators named under INQUIRIES.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by the NCI. Incomplete applications will be returned to the applicant without further consideration. If NCI staff find that the application is not responsive to the RFA, it will be returned without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NCI in accordance with the review criteria stated below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA.

Peer review for scientific and technical merit of each Program Project application will emphasize two major aspects: (1) the program as an integrated research effort focused on a central theme and (2) merit of individual research projects and core components.

AWARD CRITERIA

The anticipated date of award is July 1, 1995. Scientific merit, as reflected by the priority score; availability of funds; and programmatic priorities will be considered in making awards.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA and inquiries regarding programmatic issues to:

Susan M. Pilch, Ph.D.
Division of Cancer Prevention and Control
National Cancer Institute
Executive Plaza North, Suite 212
Bethesda, MD 20892
Telephone: (301) 496-8573
FAX: (301) 402-0553

Direct inquiries regarding fiscal matters to:

Robert E. Hawkins
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800 Ext. 213

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399, Cancer Control. Awards will be made under the authority of the Public Health Services Act, Title IV, Section 301 (Public Law 78-410, 42 USC 241 and Section 412, as amended by Public Law 99-518, 42 USC 285a-1) and administered under Federal regulations 42 CFR Part 52 and PHS grant policies 45 CFR Part 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12732 or Health Systems Agency review.

ALCOHOL RESEARCH CENTER GRANTS

NIH GUIDE, Volume 23, Number 22, June 10, 1994

RFA AVAILABLE: AA-94-008

P.T. 04; K.W. 0404003, 0710030

National Institute on Alcohol Abuse and Alcoholism

Letter of Intent Receipt Date: December 1, 1994

Application Receipt Date: January 19, 1995

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) provides grant support for Alcohol Research Centers to conduct interdisciplinary research on alcoholism and alcohol abuse. The Center grants program is interrelated with and complementary to all other research support mechanisms and scientific activities that comprise the NIAAA programs of research on the nature, causes, and consequences of alcohol abuse and alcoholism, including diagnosis, treatment, prevention, and health services research related to prevention and treatment of alcoholism.

The NIAAA currently supports 14 Centers and anticipates that the level of support for this program will not expand during this competition. Support for four of the current five-year Center grant awards will expire in late 1995. Research within each of these four Centers is organized around a central theme, respectively, adolescent alcohol abuse, alcoholism treatment, epidemiology of alcohol problems, and pathologic effects of alcohol. Applications for new Centers in these and other research areas will be accepted with applications from currently funded Centers seeking renewal support.

HEALTH PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objects of "Health People 2000," a PHS-led national activity for setting priority areas. This RFA, Alcohol Research Center Grants, is related to the priority area of alcohol abuse and alcoholism reduction. Potential applicants may obtain a copy of "Health People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Any domestic public (non-Federal) or private non-profit or for-profit institution may apply for a Center grant. However, the proposed Center must be affiliated with an institution, such as a university, medical center, or research center, that has the resources to sustain a long term, coordinated research program. An applicant institution must demonstrate the ability to attract high quality scientists from biomedical, behavioral, and/or social science disciplines who are willing to make a long term commitment to research. Women and minority investigators are encouraged to apply.

MECHANISM OF SUPPORT

A specialized Center (P50) is a comprehensive, broad-based multidisciplinary, multi-investigator, long-term program of combined research and research support activity planned around a specific major research objective or research theme. In addition to providing support for shared resources, this type of Center supports a full range of basic, developmental, clinical, and/or applied research components; allows for growth and development through pilot projects; and is intended to provide state-of-the-art leadership in the alcohol field.

FUNDS AVAILABLE

It is estimated that approximately six to seven million dollars will be available in FY 1996 to fund approximately four Centers. The total cost for a Center may not exceed \$1.7 million per year.

RESEARCH OBJECTIVES

All proposed research to be conducted within a Center must be clearly directed toward one or more of the following goals: prevalence, etiology, diagnosis, prediction, clinical course, management or treatment of alcohol abuse, alcoholism, or alcohol-related health problems; health services research; consequences of alcoholism or alcohol abuse; and factors that relate to prevention of alcohol abuse, alcoholism, or other problems associated with alcohol consumption. For example, research to improve knowledge of the impact of alcohol use on related health problems, such as liver and gastrointestinal disorders; nicotine and other drug abuse; neurological impairment; and mental disorders which co-occur with alcohol abuse disorders, is also encouraged.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by December 1, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIAAA staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to Dr. Ernestine Vanderveen at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applicants are to use grant application form PHS 398 (rev. 9/91). These forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The title and number of this RFA, Alcohol Research Center Grants, AA-94-008, must be typed in item number 2a on the face page of the PHS 398 application form.

REVIEW CONSIDERATIONS

Each center application will be reviewed by a group of experts convened by the NIAAA to evaluate the scientific and technical merit of the application. Recommendations from this review will be presented to the National Advisory Council on Alcohol Abuse and Alcoholism that will make a final recommendation to the Director, NIAAA.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Ernestine Vanderveen, Ph.D.
Centers Program
National Institute on Alcohol Abuse and Alcoholism
Willco Building, Suite 402
6000 Executive Boulevard
Rockville, MD 20892-7003
Telephone: (301) 443-1273
FAX: (301) 594-0673

Direct inquiries regarding fiscal matters to:

Edward Ellis
Office of Planning and Resource Management
National Institute on Alcohol Abuse and Alcoholism
Willco Building, Suite 504
6000 Executive Boulevard
Rockville, MD 20892-7003
Telephone: (301) 443-4703
FAX: (301) 443-3891

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.891. Awards are made under Sections 301 and 464J of the Public Health Service Act and administered under PHS policies and Federal Regulations at Title 42 CFR Part 549, "Grants for National Alcohol Research Centers;" Title 45 CFR Parts 74 and 92, "Administration of Grants;" and 45 CFR Part 46, "Protections of Human Subjects." This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

AHCPR SMALL RESEARCH GRANT PROGRAM

NIH GUIDE, Volume 23, Number 22, June 10, 1994

PA NUMBER: PAR-94-072

P.T. 34; K.W. 0730050

Agency for Health Care Policy and Research

PURPOSE

The Agency for Health Care Policy and Research (AHCPR) announces an update of its small grant program, whereby applications may be reviewed and considered for funding under an accelerated time frame.

AHCPR conducts and supports research that will enhance the quality, appropriateness, effectiveness, and cost-effectiveness of health care services and access to such services. Support for small research grants is part of AHCPR's effort to build research capacity and stimulate the development of innovative and timely research on issues related to the delivery of health care services. Small grant applications are those with total direct costs of \$50,000 or less over the project period.

AHCPR's small grant program support is designed to: (1) aid the career development of new health services researchers, (2) encourage individuals from a variety of academic and professional disciplines and programs to study complex issues with respect to health care services, (3) encourage the conduct of clinical practice-oriented research, and (4) support preliminary studies when such are required before more definitive inquiry can proceed.

Applicants who propose research that addresses priority areas that are highlighted in AHCPR program announcements will be notified of funding decisions approximately six months after receipt of applications.

This announcement supersedes "Health Services Research Priority Areas for Accelerated Small Grant Application Review" PA-91-92, which was published in the NIH Guide in May 1991 and the Federal Register on July 15, 1991. AHCPR's program for accelerated review of small conference grant applications, as announced in "Health Services Research Conference Grants" (PA-91-61) in the NIH Guide for Grants and Contracts on May 31, 1991 and the Federal Register on July 15, 1991, remains unchanged at this time.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. The AHCPR urges applicants to submit grant applications relevant to the specific health services research objectives of this initiative. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, non-profit organizations, public and private, including universities, clinics, units of State and local governments, and foundations. Applications from minority and women investigators are encouraged.

The aims of the proposed project must be distinctly different from those of any pending grant application or funded research project submitted by the principal investigator. The request may not be used to supplement currently supported projects, provide interim support for projects under review by the PHS, or obtain funding as a competing continuation of a small grant.

MECHANISMS OF SUPPORT

This Program Announcement (PA) will use the small research grant (R03) mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the proposed principal investigator. The total direct costs must not exceed \$50,000 for the entire project period. Projects should be accomplished in one to two years.

RESEARCH OBJECTIVES

Background

AHCPR's authorizing legislation provides for the use of the small grant mechanism, and permits adjustments in the procedures otherwise established for the conduct of peer review, for the purpose of encouraging the entry of individuals into the field of research, for the purpose of encouraging clinical practice-oriented research, and for such other purposes as the Administrator may determine to be appropriate.

AHCPR's use of accelerated procedures for consideration of small research grants is a response to the expressed interest of the research community in maintaining mechanisms that provide a transition: (1) to independent investigation by new researchers; or (2) for researchers accomplished in other fields who are moving into health services and health policy research. It is also intended to provide the potential for support of preliminary studies in areas for which the availability of other options is limited.

This is not the only mechanism used by AHCPR to encourage entry of investigators into health services research. Applicants should inquire about other AHCPR programs for which they may be eligible, such as National Research Service Individual Postdoctoral Fellowship Awards and Dissertation Research Grants.

Research Issues

Applicants are encouraged to investigate priority issues that have been publicized in various program announcements of AHCPR. The following announcements, which were published in the NIH Guide for Grants and Contracts, provide information on selected areas of interest:

- o "Primary Care and Health Care Reform" (PA-93-063), Vol. 22, No. 10, March 12, 1993;
- o "Cost and Financing Issues in Health Care Reform" (PA-93-45), Vol. 22, No. 4, January 29, 1993;
- o "Health Care Quality Improvement and Quality Assurance Research" (PA-93-084), Vol. 22, No. 19, May 21, 1993;
- o "Health Services for Persons with HIV Infection" (PA-93-110), Vol. 22, No. 33, September 17, 1993;
- o "Medical Malpractice and Liability Research" (PA-94-016), Vol. 22, No. 44, December 10, 1993;
- o "Health Services Research on Rural Health" (PA-92-71), Vol. 21, No. 16, May 1, 1992;
- o "Effective Dissemination of Health and Clinical Information and Research Findings" (PA-92-51), Vol 21, No. 10, March 13, 1992; and
- o "Medical Treatment Effectiveness Research -- Summary" (PA-94-074), Vol. 23, No. 22, June 10, 1994.

Applications addressing areas of interest to AHCPR covered by program announcements released subsequent to this small grant announcement also will be eligible for consideration for funding under an accelerated timeframe.

Applicants may direct inquiries regarding programmatic issues to appropriate staff. Specific individuals for each area are:

Primary care and health care reform:

Center for General Health Services Extramural Research
Carolyn Clancy, M.D.
Telephone: (301) 594-1357, ext. 133

Cost and financing issues in health care reform:

Center for General Health Services Extramural Research
Michael Hagan
Telephone: (301) 594-1354, ext. 120

Health care quality improvement and quality assurance:

Center for General Health Services Extramural Research
Bertha D. Atelsek
Telephone: (301) 594-1352, ext. 111

Health care services for persons with HIV infection:

Center for General Health Services Extramural Research
Melford J. Henderson, M.P.H., M.A.
Telephone: (301) 594-1354, extension 122

Medical malpractice and liability research:

Center for General Health Services Extramural Research
David C. Hsia, J.D., M.D., M.P.H.
Telephone: (301) 594-1354, ext. 118

Health services research on rural health:

Center for General Health Services Extramural Research
Jean G. Carmody, M.S.W.
Telephone: (301) 594-1357, ext. 130

Dissemination of health and clinical information and research findings:

Center for Research Dissemination and Liaison
Jane E. Linkletter
Telephone: (301) 594-1362

Medical effectiveness and outcomes research:

Center for General Health Services Extramural Research
James Cooper, M.D.
Telephone: (301) 594-1357, ext. 141

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of AHCPR that women and members of minority groups and their subpopulations must be included in all AHCPR-supported health services research projects involving human subjects, unless clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

A new NIH policy resulting from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) supersedes and strengthens NIH's previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which were in effect since 1990 and which AHCPR had adopted. The new NIH policy

contains some provisions that are substantially different from the 1990 policies. AHCPR plans to publish guidelines specific to AHCPR. In the interim, AHCPR will follow the NIH guidelines, as applicable.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 9, 1994 (FR 59 11146-11151) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the NIH policy from the program staff listed under INQUIRIES. AHCPR program staff may also provide additional relevant information concerning this policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 09/91) and will be accepted on or before the application receipt dates as indicated in the application kit. (State and local governments may use form PHS 5161 and follow those requirements for copy submission.) Application kits are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from Global Exchange Inc., 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814-3015, telephone (301) 656-3100, (FAX (301) 652-5264).

To be eligible for expedited processing and funding consideration, item 2a of page 1 of the application must be checked "YES;" and the PA number and the title "AHCPR Small Grants Program" must be entered.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as a component of one pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the referral office, DRG. Incomplete applications will be returned to the applicant without further consideration. Review criteria for AHCPR grant applications are: significance and originality from a scientific and technical viewpoint; adequacy of the method to carry out the project; availability of data or the proposed plan to collect data required for the project; qualifications and experience of the principal investigator and proposed staff; adequacy of the plan for organizing and carrying out the project; reasonableness of the proposed budget; and adequacy of the facilities and resources available to the applicant.

AHCPR is particularly interested in supporting new investigators and will give special consideration to proposed principal investigators (PI) who have not been designated previously as PI on any PHS-supported research project (including both R01 and R03), other than an Academic Research Enhancement Award (R15) or certain career development awards (K series) directed principally to physicians, dentists, or other clinicians with limited research experience.

The size and scope of proposed projects should be appropriate to the capabilities of the researcher and the area addressed. Applications that propose a budget that is grossly inadequate to accomplish the aims of the project will not receive favorable consideration.

Applications usually will be reviewed for scientific and technical merit by an AHCPR initial review group (IRG) composed primarily of non-Federal scientific experts. Summaries of IRG recommendations will be sent to applicants as soon as possible following IRG review.

Sec. 922 (d)(2) of the Public Health Service Act allows the Administrator to make appropriate adjustment in AHCPR's usual peer review procedures for applications whose direct costs do not exceed \$50,000. Although it is anticipated that most such applications will be reviewed by AHCPR-chartered review groups, AHCPR reserves the right to modify procedures used by these groups or to make the determination that an application warrants immediate review by Federal or non-Federal experts serving as field readers. The final determination of the method of review is made by AHCPR, and will be based upon program relevance, time constraints, uniqueness, or special opportunity associated with the application.

AWARD CRITERIA

Applications will compete for available funds with all other applications. The following will be considered in making funding decisions: quality of the proposed project as determined by peer review, availability of funds, and program balance. The earliest possible dates of award for applications are seven months from the application receipt date. In most cases, funding decisions will be made within six months of the application receipt date.

INQUIRIES

Copies of the program announcements referenced in the Research Objectives section above, as well as others released subsequent to this announcement, are available from Global Exchange Inc., 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814-3015, telephone (301) 656-3100, (FAX (301) 652-5264).

Those considering applying in response to this PA are strongly encouraged to discuss their project with AHCPR program administrators before formal submission. AHCPR welcomes the opportunity to clarify any issues or questions from potential applicants.

Direct inquiries regarding programmatic issues, including information on the policy of inclusion of women and minorities in study populations, to:

Norman W. Weissman, Ph.D.
Center for General Health Services Extramural Research
Agency for Health Care Policy and Research
2101 E. Jefferson Street, Suite 502
Rockville, MD 20852
Telephone: (301) 594-1349, ext. 106

Direct inquiries regarding fiscal/administrative matters to:

Ralph Sloat
Agency for Health Care Policy and Research
2101 E. Jefferson Street, Suite 601
Rockville, MD 20852
Telephone: (301) 594-1447

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.180 and 93.226. Awards are authorized under the Public Health Service Act, Title IX, as amended, (42 U.S.C. 299-299c-6), and Section 1142 of the Social Security Act (42 U.S.C. 1320b-12). Awards are administered under the PHS Grants Policy Statement and Federal Regulations 42 CFR Part 67, Subpart A and 45 CFR Part 74 (Part 92 for State and local governments). This program is not subject to the intergovernmental review requirements of Executive Order 12372.

CENTERS FOR RESEARCH ON SERVICES FOR PEOPLE WITH MENTAL HEALTH DISORDERS

NIH GUIDE, Volume 23, Number 22, June 10, 1994

PA NUMBER: PAR-94-073

P.T. 04; K.W. 0730057, 0710030

National Institute of Mental Health

Application Receipt Date: October 1

THIS IS A NOTICE OF AVAILABILITY OF A PROGRAM ANNOUNCEMENT (PA). IT IS ONLY AN ABSTRACT OF THE PA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE PA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE PAR MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Mental Health (NIMH) announces the availability of support for multidisciplinary Centers for Research on Services for People with Mental Disorders. The purpose of these Centers is to promote, develop, and conduct multidisciplinary research that can help to improve the organization, financing, delivery, quality, effectiveness, and outcomes of services for persons of all ages with mental disorders.

This program announcement supersedes and replaces NIMH program announcements PA-92-94, Centers for Research on Services for People with Severe Mental Disorders, and PA-92-20, Centers for Research on Mental Health Services for Children and Adolescents. Its scope is broader than these two earlier program announcements because discussions of health care reform have emphasized the need for the NIMH to develop a center program that includes services provided in general health settings and other agency, institutional, and community contexts.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Centers for Research on Services for People with Mental Disorders, is related to the priority area of mental health and mental disorders. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY

Applications may be submitted by for-profit and non-profit domestic organizations and by public and private institutions, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications from minority and women investigators are encouraged.

MECHANISM OF SUPPORT

This PA will use the National Institutes of Health (NIH) Specialized Center (P50) mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for each application submitted in response to this program announcement may not exceed five years.

The funding cap for a Center for Research on Services for People with Mental Disorders is \$600,000 in direct costs for the initial project year, with annual increases of four percent thereafter, plus negotiated institutional indirect costs. Applications that request direct costs in excess of this amount will be returned to the applicant without review.

RESEARCH OBJECTIVES

Examples of the types of services research issues that might be addressed by a Center are listed in the RFA. It is expected that additional relevant and important research topics will be identified by investigators who respond to this program announcement.

A Center should be planned and organized for the purpose of addressing major gaps in scientific knowledge and needs in the field of mental health services research on people with mental disorders. Centers must be multidisciplinary.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

APPLICATION PROCEDURES

Applicants are to use the research grant application form PHS 398 (rev. 9/91). Application kits containing the necessary forms may be obtained from the office of sponsored research at most universities, colleges, medical schools, and other major research facilities and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The number and title of this program announcement, PAR-94-073 "Centers for Research on Services for People with Mental Health Disorders, must be typed in item number 2a on the face page of the PHS 398 application form.

Applications for a Center grant must include: (1) an overall organizational and research plan, and (2) separate, more detailed plans for the research core areas that are proposed as foci for Center activity. For purposes of the page limitations of sections 1 through 4 of PHS 398, the overall Center research plan and organizational plan should be considered one component with a 25-page limit. A maximum of 25 additional pages may be used for each research core area that the Center will address.

The signed original and five legible copies of the completed application must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be reviewed for scientific and technical merit by an NIMH initial review group (IRG) composed primarily of non-Federal scientific experts. A second level review will be by the National Advisory Mental Health Council; review by Council may be based on policy considerations as well as scientific merit. By law, only applications recommended for consideration for funding by the Council may be supported. Summaries of IRG discussions are sent to applicants as soon as possible following IRG review.

AWARD CRITERIA

In making funding decisions, quality of the proposed project, availability of funds, and program balance among research areas of the announcement will be considered.

Applications will be received and reviewed once a year according to the following NIMH schedule:

Application Receipt Date:	October 1
Initial Review:	February/March
Advisory Council Review Date:	May/June
Earliest Start Date:	July 1

INQUIRIES

Written and telephone requests for the PA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the PA and inquiries regarding programmatic issues to:

Thomas L. Lalley
Services Research Branch
National Institute of Mental Health
5600 Fishers Lane, Room 10C-06
Rockville, MD 20857
Telephone: (301) 443-3364

Direct inquiries regarding fiscal matters to:

Diana Trunnell
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-08
Rockville, MD 20857
Telephone: (301) 443-3065

Grants must be administered in accordance with the PHS Grants Policy Statement (rev. 4/94). Federal Regulations at 42 CFR Part 52, "Grants for Research Projects," and 45 CFR Parts 74 and 92 concerning administration of grants, are applicable to these awards. This announcement is not subject to the intergovernmental requirements of Executive Order 12372, as implemented through DHHS regulations at 45 CFR Part 100, or Health Systems Agency review.

MEDICAL TREATMENT EFFECTIVENESS RESEARCH - SUMMARY

NIH GUIDE, Volume 23, Number 22, June 10, 1994

PA NUMBER: PA-94-074

P.T. 34; K.W. 0730021, 0408006

Agency for Health Care Policy and Research

PURPOSE

The Agency for Health Care Policy and Research (AHCPR) has ongoing interest in research under the Medical Treatment Effectiveness Program (MEDTEP). This program announcement (PA) outlines the common themes inherent in all MEDTEP projects and identifies major ongoing areas of research. MEDTEP research encompasses three main areas of emphasis: (1) determining what clinical interventions are most effective, cost effective, and appropriate; (2) methods and data to advance effectiveness research; and (3) dissemination and evaluation of the impact of research findings on clinical practice and outcomes. This PA serves as a general reference for other publications and contacts regarding current MEDTEP research interests and award mechanisms.

This Program Announcement (PA) supersedes the "Medical Treatment Effectiveness Research" announcement published in the Federal Register of August 14, 1990 (FR 55 33170-33172).

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. The AHCPR urges applicants to submit grant applications with relevance to the specific objectives of this initiative. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-004374-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign non-profit organizations, public and private, including universities, clinics, units of State and local governments, non-profit firms, and non-profit foundations. Applications from minority and women investigators are encouraged. Foreign applicants are advised to contact the AHCPR Grants Management Officer regarding limitations and special requirements (see INQUIRIES).

MECHANISM OF SUPPORT

The research project grant (R01) mechanism, which may provide support for up to five years, is the principal mechanism of support for MEDTEP research. The small grant (R03) mechanism is available for projects that do not exceed two years and \$50,000 in direct costs for the entire project period. Responsibility for planning, direction, and execution of the proposed project is solely that of the applicant.

In addition, AHCPR may issue requests for applications (RFAs) and PAs that announce new MEDTEP program interests and/or the availability of other mechanisms of support for MEDTEP research. For further information on specific areas of MEDTEP research, contact Dr. Richard Greene (see INQUIRIES); or Dr. Norman Weissman or Ms. Zucker as indicated below.

RESEARCH OBJECTIVES

MEDTEP Research Themes

Medical effectiveness research is a major component of the health services research agenda of AHCPR. MEDTEP grew out of awareness of significant unexplained variations in clinical (medical, nursing, and allied health) practice and the inadequacy of scientific evidence to support many practices and procedures. MEDTEP projects assess the relative effectiveness, cost effectiveness, and appropriateness of available strategies for the prevention, diagnosis, treatment, and management of illness, in terms of patient outcomes. While MEDTEP research projects vary in focus, size, scope, methods, and complexity, all are expected to be:

Generalizable: "Effectiveness" research is concerned with the outcomes that can be expected in typical patients, receiving care in typical clinical situations, not with outcomes that can only be achieved in selected patients and in controlled clinical situations. Thus, a critical feature of all MEDTEP projects is that the questions have broad applicability and the research design supports wide generalization of the findings.

Pragmatic: MEDTEP projects address questions that have high clinical and policy significance and are designed with attention to the eventual implementation of findings. They obtain empirical evidence or strengthen the science base in ways that can directly contribute to improved patient outcomes and decisionmaking processes (including practice guidelines), and to a more equitable and cost-effective health care system. The usefulness of MEDTEP research stems, in part, from MEDTEP's requirement that the clinical problems and practices addressed are common and costly, and from attention to the realities of clinical practice.

Patient-Centered: MEDTEP research evaluates health care in terms of outcomes that emphasize the patient's experience and perspectives. In addition to survival, morbidity, and complications, MEDTEP studies consider patient-reported symptom relief, functional capacity, quality of life, satisfaction with care, and economic burden. Demographic, social and cultural characteristics, as well as personal preferences are important independent variables.

Multidisciplinary: MEDTEP research requires theoretical and practical understanding of a wide range of clinical and non-clinical variables that determine the structure, processes, and outcomes of health care. Studies typically involve a team of researchers who bring the knowledge and methodological expertise of both the clinical and social sciences, plus understanding of the perspectives of patients, providers, and policymakers.

Types of Studies

MEDTEP research encompasses three main areas of emphasis: (1) determining what clinical interventions are most effective, cost effective, and appropriate; (2) methods and data to advance effectiveness research; and (3) dissemination and evaluation of the impact of research findings on clinical practice and outcomes.

1. Clinical Studies

All MEDTEP clinical studies address the basic MEDTEP themes described above to obtain evidence for or against the effectiveness, cost effectiveness, and appropriateness of available interventions. Most focus on a particular disease or clinical condition and assess the outcomes associated with different interventions that are available for its prevention, diagnosis, treatment, and/or management. Some MEDTEP clinical studies focus on established technologies or procedures. Of interest are conditions or procedures that are common and costly, either in the general population or in a major subpopulation. Major categories of MEDTEP clinical studies are described below.

Patient Outcomes Research Teams (PORTs) and PORT-1Is. Between 1989 and 1992, AHCPR awarded fourteen special MEDTEP projects known as Patient Outcomes Research Teams (PORTs). PORTs are distinguished from other MEDTEP clinical studies by their broad scope, multi-method approach to patient outcomes questions, and by the standard five year model they follow. AHCPR does not anticipate award of additional projects that use the PORT model.

In July 1993, AHCPR issued an RFA initiating a new generation of MEDTEP research, called "PORT-II," with the first awards to be made this year. An ongoing PA, "Medical Treatment Effectiveness Research -- PORT-II," was published in the NIH Guide for Grants and Contracts, Volume 23, Number 18, May 13, 1994. PORT-1Is continue the PORT tradition by addressing important clinical questions and breaking new methodological ground. They are distinguished from the original PORTs by their individualized research strategies and from other MEDTEP clinical projects by the expected direct impact of the empirical evidence they obtain, on clinical practice, patient outcomes, and health care policy.

PORT-1Is are not feasible or desirable in all clinical areas. There must be sufficient existing information to permit the formulation of effectiveness questions and design of a research strategy tailored to the clinical problem and the population at risk, so that convincing evidence of optimal patient care can be realistically expected within the project period. PORT-1Is focus on the establishment of direct linkages between practice and outcomes and on research methods that facilitate direct comparisons of two or more distinct clinical strategies, e.g., medical vs. surgical treatment. For information on MEDTEP clinical studies, including PORT-1Is, contact the Center for Medical Effectiveness Research (CMER), see INQUIRIES.

Other MEDTEP Clinical Studies. The majority of MEDTEP clinical studies are designed to build the science base in areas where a PORT-II is not currently feasible or desirable. This includes research designed to document patterns of practice, describe the natural history of diseases, synthesize the evidence for various clinical strategies, or answer relatively discrete effectiveness questions. Major ongoing program areas focus on pharmaceutical therapy, minority health, and primary care.

AHCPR's program of studies on pharmaceutical therapy, established in 1992, focuses on the effectiveness and cost effectiveness of available pharmaceutical interventions, especially the relationships among drug therapy, other pharmaceutical services, and patient outcomes. Studies address preventive, acute, or chronic treatment in inpatient, ambulatory, or long-term care settings. For further guidance, contact program staff listed under INQUIRIES.

In 1991, AHCPR established a research program focused on the effectiveness of current clinical practice for health conditions of special significance among racial and ethnic minorities. This program is highlighted by the eleven MEDTEP Research Centers on Minority Populations, which train minority investigators who are new to outcomes research to develop and conduct effectiveness research. Although additional MEDTEP Minority Centers are not anticipated, AHCPR has continuing interest in studies of the effectiveness of care related to special problems in minority populations. For information, contact CMER program staff or the Associate Administrator for Minority Health, Dr. Morgan Jackson, telephone 301-594-6665.

AHCPR's program of primary care research includes, but is not limited to, effectiveness research topics. MEDTEP primary care studies focus on the effectiveness and cost effectiveness of care for conditions that are often undifferentiated, as they present in unselected or nonreferred populations, in primary care settings, and the role of primary care physicians in enhancing the effectiveness and cost effectiveness of care. For information, contact the Center for General Health Services Extramural Research (CGHSER), Dr. Norman Weissman, Director, telephone 301-594-1349, ext. 109.; or CGHSER, Division of Primary Care, Dr. Carolyn Clancy, Director, telephone 301-594-1357, ext. 137.

2. Methodological Studies

Effectiveness research frequently requires new kinds of data and analysis, and new applications of existing tools. MEDTEP supports projects that aim to strengthen or define the limits of existing data and develop or test measurement and data collection instruments, and analytic methods useful for outcomes research. For example, MEDTEP projects may develop new outcomes measures, methods for linking or enhancing existing databases, methods to assess patient preferences, or methods for cross-cultural or international comparisons of patient outcomes. Methodological work may be the main focus of a project or may be embedded in a larger project. For information on these studies, contact CMER program staff or CGHSER, Dr. Norman Weissman (see above).

3. Dissemination and Evaluation Studies

Some MEDTEP projects focus on approaches or technologies for achieving optimal dissemination and integration of new knowledge into practice. This includes research, demonstrations, and evaluations that examine issues of diffusion, awareness, acceptance, and adoption of research findings and clinical practice guidelines by health care providers and consumers. For example, projects may examine the role of opinion leaders and practitioner study groups in influencing practice, or various approaches to enhancing patient participation in health care decisions. MEDTEP also supports studies to develop and evaluate clinical practice guidelines, information systems, and clinical evaluation tools designed to help practitioners and consumers make better health care decisions. Contact the Center for Research Dissemination and Liaison, Ms. Phyllis Zucker, Director, telephone 301-594-1360, regarding dissemination studies. Contact CGHSER, Dr. Norman Weissman, regarding evaluation studies (see above).

Research Methods

MEDTEP studies draw on a wide range of research methods, especially those used in the clinical, evaluative, and social sciences. The research design may be experimental, quasi-experimental, observational, or a combination of designs. Any appropriate type(s) of statistical analysis, modeling, or synthesis may be proposed. Types and sources of data may include: new, established, or adapted surveys of patients or providers; clinical data obtained prospectively, or from clinical registries, practice-based networks, or other health care providers; administrative data maintained by providers, insurers, or institutions; and published research findings. Laboratory-based studies are not appropriate.

Applications must be explicit and detailed in describing data, methods, and tools for data collection and analysis. The research plan must be justified in terms of potential for answering the research questions under study.

Applicants who propose to use Medicare or Medicaid data must specify the required data files and explore the availability and cost of obtaining these data with the Health Care Financing Administration (HCFA). The estimated cost must be presented, along with documentation from HCFA, as part of the grant application. This cost should not be included in the total budget request for the project. For more information about data budgets, contact Mr. Ralph L. Sloat, AHCPR Grants Management Officer (see INQUIRIES).

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of AHCPR that women and members of minority groups must be included in all AHCPR supported health services research projects involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

A new NIH policy resulting from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) supersedes and strengthens NIH's previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which were in effect since 1990 and which AHCPR had adopted. The new NIH policy contains some provisions that are substantially different from the 1990 policies. AHCPR plans to publish guidelines specific to AHCPR. In the interim, AHCPR will follow the NIH guidelines, as applicable.

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the Federal Register of March 9, 1994 (FR 59 11146-11151) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the NIH policy from the AHCPR program staff listed under INQUIRIES. AHCPR program staff may also provide additional relevant information concerning this policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91), and will be accepted at the standard application deadlines as indicated in the application kit. (State and local government agencies may use form PHS 5161 and follow accompanying requirements for submission.) Application kits are available at most institutional offices of sponsored research; from the Office of Grant Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301-594-7248; and for AHCPR applications from Global Exchange Inc., 7910 Woodmont Ave Suite 400, Bethesda, MD 20814-3015, telephone 301-656-3100 (FAX 301-652-5264).

The completed, signed, original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the referral office, DRG. Incomplete applications will be returned to applicants without further consideration.

General review criteria for all grant applications are: significance and originality from a scientific and technical viewpoint; adequacy of the method(s); availability of data or adequacy of plan to collect required data; qualifications and experience of the principal investigator and proposed staff; adequacy of the plan for organizing and managing the

project; reasonableness of the proposed budget; and adequacy of the facilities and resources available to the applicant.

An appropriate peer review group will evaluate applications for scientific/technical merit in accordance with the general criteria stated above, and any special review criteria applicable to an individual mechanism or as listed in specific announcements. Applications assigned to the AHCPR and requesting total direct costs in excess of \$250,000 will be reviewed by AHCPR's National Advisory Council for Health Care Policy, Research, and Evaluation, as may applications requesting total direct cost in excess of \$50,000.

Special Review Criteria

Applicants are advised to refer to individual announcements and to contact the staff offices listed below regarding special review criteria.

AWARD CRITERIA

In making funding decisions, quality of the proposed project as determined by peer review, program balance, and availability of funds will be considered.

INQUIRIES

Those considering applying in response to this PA are strongly encouraged to discuss their project with AHCPR program administrators; AHCPR welcomes the opportunity to clarify any issues or questions from potential applicants.

Direct inquiries regarding programmatic issues, including information on the policy of inclusion of women and minorities in study populations, to:

Richard Greene, M.D., Ph.D.
Center for Medical Effectiveness Research
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 605
Rockville, MD 20852
Telephone: (301) 594-1485

Direct inquiries regarding fiscal matters, including budget justification for HCFA data, to:

Ralph L. Sloat
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 601
Rockville, MD 20852
Telephone: (301) 594-1447

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.180 and 93.226. Awards are made under authorization of the Public Health Service Act, Title IX (42 U.S.C. 299-299c-6 and Section 1142 of the Social Security Act (42 U.S.C. 1320b-12)). Awards are administered under the PHS Grants Policy Statement; and Regulations 42 CFR Part 67, Subpart A, and 45 CFR Part 74 (45 CFR Part 92 for State and local governments). This program is not subject to the intergovernmental review requirements of Executive Order 12372.

INTERVENTIONS TO IMPROVE ASTHMA MANAGEMENT AND PREVENTION AT SCHOOL

NIH GUIDE, Volume 23, Number 22, June 10, 1994

BAA AVAILABLE: NHLBI-HR-94-15

P.T. 34; K.W. 0715013, 0745027

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) plans to use a Broad Agency Announcement (BAA) research and development contract program to develop and evaluate innovative programs to assure optimal asthma management and prevention at school.

This is a correction of the announcement for Broad Agency Announcement (BAA) that appeared in the NIH Guide for Grants and Contracts, Vol 23, No. 18, May 13, 1994. The BAA will be available on or about June 9, 1994, with proposals due on or about September 7, 1994. Written requests for the BAA must include three self-addressed mailing labels and cite BAA NHLBI-HR-94-15.

Requests for copies of the BAA are to be addressed to:

Mr. Craig Miron
Contracts Operation Branch
National Heart, Lung and Blood Institute
7550 Wisconsin Avenue, Room 200
Bethesda, MD 20892

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

***5333 Westbard Avenue
Bethesda, MD 20816***



NIH GUIDE

For Grants and Contracts

LIBRARY

JUN 21 1994

National Institutes of Health

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NIH Guide
Printing & Reproduction Branch
National Institutes of Health Room B4BN23,
Building 31, Bethesda, Maryland 20892

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 23
June 17, 1994

RICHARD W MURRY

340189
81350E

929 WILD FOREST DRIVE
GAITHERSBURG MD 20879 3209

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

THE PUBLIC HEALTH SERVICE (PHS) STRONGLY ENCOURAGES ALL GRANT RECIPIENTS TO PROVIDE A SMOKE-FREE WORKPLACE AND PROMOTE THE NON-USE OF ALL TOBACCO PRODUCTS. THIS IS CONSISTENT WITH THE PHS MISSION TO PROTECT AND ADVANCE THE PHYSICAL AND MENTAL HEALTH OF THE AMERICAN PEOPLE.

THE NIH GUIDE FOR GRANTS AND CONTRACTS: INTENT TO MODIFY

NIH GUIDE, Volume 23, Number 23, June 17, 1994

P.T. 34; K.W. 1014006, 1004017

National Institutes of Health

PURPOSE

The National Institutes of Health intends to modify the NIH Guide for Grants and Contracts on August 1, 1994. The format of Request for Applications (RFAs) and Program Announcements (PAs) will not be changed, but increased emphasis on electronic access of those documents will be implemented. The purpose of the changes is to improve the timeliness and accuracy of information dissemination and reduce production costs.

BACKGROUND

The printed edition of the weekly NIH Guide for Grants and Contracts now includes notices, PAs, Notices of Availability (NA) of RFAs, and NAs of Requests for Proposals (RFP) and is mailed to approximately 34,000 subscribers. Although first class postal service is used, copies of the printed version may not be received until a week or more following publication.

Currently, a delimited, electronic edition of the NIH Guide, which includes RFAs in addition to NA/RFAs, is sent via a LIST to individuals and university offices of sponsored research. The NIH Guide is also available on a public access electronic bulletin board and on the NIH GOPHER on the Internet. Through these sources, the NIH Guide, including the full text of RFAs and PAs, is available nationwide within a day of publication.

INTENDED MODIFICATIONS

Content of the NIH Guide

The printed edition of the NIH Guide will contain notices and brief NA/RFAs and NA/PAs. The NAs will include a brief summary of the purpose of the RFA or PA; the application receipt date, anticipated number of awards, and funds available for RFAs; and information about how to obtain a copy of the RFA or PA. The electronic edition will include the contents of the printed edition and the complete text of PAs and RFAs.

Access to the NIH Guide

PAs and RFAs will be available in print and via email from the NIH contacts listed in each NA in the printed edition. The NIH will send one copy of the printed edition of the NIH Guide to each major component of each Institution, primarily to the Offices of Sponsored Research or the equivalent, and institutions not on the list of institutional contacts maintained by the NIH may request subscriptions. The current subscription list for the printed edition will be terminated.

The electronic edition of the NIH Guide, including the RFAs and PAs, will be available to individuals via a LISTSERV subscription list, the NIH Grant Line electronic bulletin board, and the NIH Gopher Server. Current subscribers to the printed edition are encouraged to establish a preferred route to the electronic edition of the NIH Guide as soon as possible and cancel subscriptions to the printed edition.

ELECTRONIC ACCESS TO THE NIH GUIDE FOR GRANTS AND CONTRACTS

1. NIHGDE-L is now an open list.

The NIHGDE-L list is now open for subscriptions from individuals. To minimize the possibility of errors, it is best for each person to subscribe him/herself to the list. Subscribing and unsubscribing to/from a list is done via e-mail. BITNET users should send mail to LISTSERV@JHUVM, and Internet users to LISTSERV@JHUVH.HCF.JHU.EDU. To subscribe to the E-Guide list, the text of the mail should be:

SUBSCRIBE NIHGDE-L First-name Last-name

The First & Last names should be in upper & lower case; e.g.:

SUBSCRIBE NIHGDE-L Bill Jones

This will register the e-mail address from which the mail was sent for E-Guide distribution. If you wish to have the E-Guide sent to an address from which mail cannot be sent (e.g., an internal distribution list), send mail to WKJ@NIHCU (BITNET) or WKJ@CU.NIH.GOV (Internet). To remove yourself from this list, send mail to LISTSERV@JHUVM (or LISTSERV@JHUVH.HCF.JHU.EDU) containing as the text:

UNSUBSCRIBE NIHGDE-L

2. Table of Contents list established.

Some users who subscribed to the NIHGDE-L list had problems with the volume of mail that was received each week. They would prefer to see a table of contents, and access the NIH Guide files via Gopher when necessary. For that purpose, the NIHTOC-L list has been established at the NIH. It will contain only the table of contents for each week's NIH Guide. It is an open list that one can subscribe to by sending mail to LISTSERV@NIHLIST or LISTSERV@LIST.NIH.GOV (Internet). The mail should contain as text:

If you do subscribe to the NIHTOC-L list and are already subscribed to the NIHGDE-L list, you will probably want to UNSUBSCRIBE from that list.

3. NIH Grant Line Bulletin Board

The NIH Grant Line includes information about NIH extramural programs, including the NIH Guide for Grants and Contracts. A new feature on the NIH Grant Line allows the rapid transmission of files via Bitnet or Internet to a Bitnet or Internet address instead of downloading via a modem.

To access the NIH Grant Line, the terminal emulator must be configured as follows: 1200 or 2400 baud, even parity, 7 data bits, 1 stop bit, half duplex. Using the procedure specified in the communication software, dial 1-301-402-2221. When a response indicates that a connection has been made, type ,GEN1 (the comma is mandatory) and press ENTER; the NIH system will prompt for INITIALS?. Type BB5 and press ENTER. A prompt will ask for ACCOUNT? Type CCS2 and press ENTER.

Messages and a menu will be displayed that allow one to read Bulletins and download Files. Back issues of the NIH Guide are found in different Directories. GUIDE90 has issues going back to July 6, 1990; GUIDE91, GUIDE92, and GUIDE93 have all issues for each year. Type F (for FILES) to access any of the files that are arranged into directories. To get an overview of the kinds of information available, type D (for Directory).

Access to NIH Grant Line via the Internet

To access the NIH Grant Line in an interactive Internet session, Telnet to WYLBUR.CU.NIH.GOV and, when a message has been received that the connection is open, type VT100. At the INITIALS? prompt, type BB5 and at the ACCOUNT? prompt, type CCS2. This puts the user into the NIH Grant Line.

4. NIH Gopher

The NIH Gopher contains information about the NIH, including the NIH Guide for Grants and Contracts, and has text searching capability. One can tunnel to the NIH Gopher, if one has access to a system with Gopher. Local computer support staff should be consulted for additional information.

INQUIRIES

For additional information or comment on the intended modifications, direct inquiries to:

Claudia Blair, Ph.D.
Director, Institutional Affairs Office
National Institutes of Health
Building 1, Room 328
Bethesda, MD 20892
Telephone: (301) 496-5366
FAX: (301) 402-2831
email: ubl@nihcu.bitnet or ubl@cu.nih.gov

Myra Brockett
Institutional Affairs Office
National Institutes of Health
Building 1, Room 328
Bethesda, MD 20892
Email: q2c@nihcu.bitnet or q2c@cu.nih.gov

For additional information about the NIH Grant Line Bulletin Board, direct inquiries to:

John C. James, Ph.D.
Assistant Director for Special Projects
Division of Research Grants
Westwood Building, Room 109
Bethesda, MD 20892
Telephone: (301) 594-7270
FAX: (301) 594-7384

PROGRAM PROJECT GRANT APPLICATION GUIDELINES

NIH GUIDE, Volume 23, Number 23, June 17, 1994

P.T. 34; K.W. 0725000, 1014006

National Institute of Environmental Health Sciences

The National Institute of Environmental Health Sciences (NIEHS) announces the new NIEHS Program Project Grant Application Guidelines. These guidelines supersede all previous versions. The purpose of this notice is to highlight some important changes regarding program project applications to the NIEHS.

Applications Receipt Dates: Applications for program project grants are accepted by the NIEHS only on June 1 and October 1 of each year. Applications for program project grants will NOT be accepted by the NIEHS for the February 1 receipt date. This date is reserved for receipt of NIEHS center grant applications.

Site Visits: Although historically the NIEHS has utilized site visits as the primary means of initial review of program project applications, beginning with the June 1, 1994 receipt date, site visits will only be conducted in exceptional circumstances. The standard practice will be to conduct the initial review without site visits. Therefore, it is imperative that applications be very carefully and thoroughly prepared.

Submission of additional information prior to initial review: The new guidelines contain specific instructions for submission of additional information prior to the initial review of the application.

Supplemental Applications: Supplemental applications will be accepted only with prior concurrence of NIEHS program staff.

INQUIRIES

To obtain a copy of the Program Project Grant Application Guidelines and for specific questions about application procedures, contact:

Thorsten Fjellstedt, Ph.D.
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-0131
FAX: (919) 541-2843

NATIONAL ANIMAL WELFARE EDUCATION WORKSHOP

NIH GUIDE, Volume 23, Number 23, June 17, 1994

P.T. 42; K.W. 0201011, 1014003

National Institutes of Health

The National Institutes of Health (NIH), Office of Extramural Research (OER), Office for Protection from Research Risks (OPRR) is cosponsoring a National Animal Welfare Education Workshop with The Department of Veterans Affairs. The workshop is open to all persons involved in the management and/or oversight of an institutional animal care and use program including institutional administrators, members of Institution Animal Care and Use Committees, laboratory animal veterinarians, investigators, and technicians.

DATES: August 4-5, 1994

TOPIC: Sharing Animal Welfare Responsibilities Between Affiliated Institutions

LOCATION

Portland Marriott Hotel
1401 SW Front Avenue
Portland OR
Telephone: (503) 226-7600 or 1-800-228-9290

SPONSOR

Department of Veterans Affairs

REGISTRATION

Ms. Margaret Doherty
Department of Veterans Affairs Medical Center
Veterinary Medical Unit (151-2)
3710 SW U.S. Veterans Hospital Road
Portland OR 97201
Telephone: (503) 220-8262 Ext. 7610
FAX: (503) 273-5351

FEE: \$150 - Regular; \$100 - Students and Technicians

Registration fee includes workshop materials, two continental breakfasts, one lunch, one wine and cheese social, and refreshment breaks.

DESCRIPTION: The workshop will explore the relationships among Academic, Government, and Industry as they pertain to the care and use of laboratory animals and animal research facilities and programs. The speakers will focus on issues such as assuming responsibility; VA vs. Academia; building shared institutional animal care and use committees; proprietary information; and the regulatory agencies' perspective and oversight.

INQUIRIES

For further information concerning future NIH/OPRR Animal Welfare Education Workshops, contact

Mrs. Roberta Sonneborn
Office of Protection from Research Risks
National Institutes of Health
Building 31, Room 5B63
Bethesda, MD 20892
Telephone: (301) 496-7163
FAX: (301) 402-2803

NATIONAL HUMAN SUBJECT PROTECTIONS WORKSHOPS

NIH GUIDE, Volume 23, Number 23, June 17, 1994

P.T. 42; K.W. 0783005

National Institutes of Health
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

DATES: July 11, 12, 13, 1994

LOCATION

Mall of American Grand Hotel, Bloomington, MN

SPONSORS

University of Minnesota of Minneapolis, Minneapolis, MN
American Indian Health Care Association, St. Paul, MN
Indian Health Service, Albuquerque, NM
Office of Research on Minority Health, NIH, Bethesda, MD

CONTACT

Office of Continuing Medical Education
University of Minnesota
Radisson Hotel Metrodome, Suite 107
615 Washington Avenue, SE
Minneapolis, MN 55414
Telephone: (612) 626-7600 or (800) 776-8636

TITLE: Contemporary Issues on Existing and New Research Guidelines on Women and Minority Groups: Special Emphasis on American Indians

DESCRIPTION: The Conference will examine existing NIH research guidelines, and discuss contemporary issues in the research environment. There will be IRB training; conference participants will be in small mock IRBs to review three protocols, with facilitation by experienced IRB staff. The Conference will examine how protecting American Indian individuals and communities by IRBs and community participation: (1) increases research benefit, (2) decreases research risk, and (3) improves quality of the research. Because Native (American Indian and Canadian First Nation) people are covered by the new NIH guidelines about inclusion of women and minorities in research, the Conference will also examine that policy in depth. The focus on Native communities and volunteers will illuminate how the new Guidelines, current IRB regulations, and community involvement fit together in practice.

INQUIRIES

For further information regarding these workshops or future NIH/FDA National Human Subject Protections Workshops, contact:

Ms. Darlene M. Ross
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 5B63
Bethesda, MD 20892
Telephone: (301) 496-8101

REMINDER AND UPDATE: REQUIREMENT FOR INSTRUCTION IN THE RESPONSIBLE CONDUCT OF RESEARCH IN NATIONAL RESEARCH SERVICE
AWARD INSTITUTIONAL TRAINING GRANTS

NIH GUIDE, Volume 23, Number 23, June 17, 1994

P.T. 44; K.W. 1014004, 1014006

National Institutes of Health

This is a republication of the notice that appeared in the NIH Guide for Grants and Contracts, Vol. 21, No. 43, November 27, 1992.

Since July 1990, the National Institutes of Health (NIH) has required all applications for Institutional National Research Service Award (NRSA) Research Training Grants (T32, T34) to include a description of a program to provide instruction in the responsible conduct of research. This requirement was announced in the NIH Guide for Grants and Contracts on December 22, 1989 (Vol. 18, No. 45), and again on August 17, 1990 (Vol. 19, No. 30).

With this notice, the NIH updates and reinforces the commitment to ensure that all NRSA supported trainees are provided an opportunity for training in the responsible conduct of research. Plans for instruction in the responsible conduct of research will continue to be required in all applications for institutional NRSA research training grants. But, beginning with applications for research training grants received on or after January 10, 1993, this requirement will be modified as follows:

- o Applications without plans for instruction in the responsible conduct of research will be considered incomplete and will be returned to the applicant without review.

- o Every predoctoral and postdoctoral NRSA trainee supported by a T32 or T34 institutional research training grant must receive instruction in the responsible conduct of research.

- o Plans that incorporate instruction in the responsible conduct of research for all graduate students and postdoctorates in a training program or department, regardless of the source of support, are particularly encouraged.

- o Although the NIH will not establish specific curriculum or format requirements, all programs are strongly encouraged to consider instruction in the following areas: conflict of interest, responsible authorship, policies for handling misconduct, policies regarding the use of human and animal subjects, and data management.

- o Plans must address: the subject matter of the instruction, the format of the instruction, the degree of faculty participation, trainee attendance, and the frequency of instruction. A rationale for the proposed plan of instruction must be provided.

- o Progress reports on the type of instruction provided, topics covered, and other relevant information such as attendance by trainees and faculty participation must be included in future competing and noncompeting applications.

The procedures for the review of the plans for instruction in the responsible conduct of research will be as follows:

- o At initial review, one or more reviewer(s) will be assigned to evaluate the plan for providing training in the responsible conduct of research.

- o The plan will be discussed after the overall determination of merit so that the quality of the plan will not be a factor in the determination of the priority score.

- o The assessment of the plan will include consideration of the appropriateness of the topics, the format, the amount and nature of faculty participation, and the frequency and duration of instruction. Plans will be judged either acceptable or unacceptable.

- o The plan and its acceptability will be described in an administrative note in the summary statement.

- o Regardless of the priority score, applications with unacceptable plans will not be funded until a revised, acceptable plan is provided by the applicant. The acceptability of the revised plan will be judged by staff within the awarding component at the NIH.

INQUIRIES

The contact for general information about this policy is:

Dr. Walter T. Schaffer
Director, Research Training and Special Programs Office
National Institutes of Health
Building 31, Room 5B44
Bethesda, MD 20892
Telephone: (301) 496-9743

Questions regarding a specific training program or grant application should be directed to the appropriate NIH Institute.

National Institutes of Health

This notice is a republication, with minor modifications, of a March 1990 issuance on this subject. It is being reissued to emphasize its continuing importance.

Organizations receiving grant or contract awards are responsible for protecting their personnel from hazardous conditions. The Government is not legally liable for accidents, illnesses, or claims arising out research performed under its awards, but the National Institutes of Health (NIH) is nonetheless aware that a variety of hazards threaten the safety and health of both laboratory and clinical research personnel. Accordingly, the guidelines that follow are designed to (1) identify potential hazards, (2) advise awardee organizations and investigators of certain standards that should be considered in order to address particular health and/or safety concerns, and (3) emphasize that concerns about potentially hazardous conditions could result in grant or contract funding delays until those concerns have been resolved to the satisfaction of the awarding component.

1. Sources of potential danger to research personnel include the following classes of hazard:
 - a. Biohazards (e.g., Human Immunodeficiency Virus (HIV), other infectious agents, oncogenic viruses).
 - b. Chemical hazards (e.g., carcinogens; chemotherapeutic agents; other toxic chemicals; flammable or explosive materials).
 - c. Radioactive materials.
2. The following guidelines and standards contain information designed to assist grantees and contractors in providing a safe work environment for research personnel. Therefore, depending upon the particular safety hazard at issue, grantees and contractors are expected to consult these guidelines. They may be obtained from:

Division of Safety
Office of Research Services
National Institutes of Health
Building 31, Room 1C02
Bethesda, MD 20892

- a. Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Centers for disease Control and the National Institutes of Health. HHS Publication No. (CDC) 93-8395.
- b. Recommendations for Prevention of HIV Transmission in Health-Care Settings. Morbidity and Mortality Report, August 21, 1987, Vol. 35, No. 2S.
- c. Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings. Morbidity and Mortality Weekly Report, June 24, 1988, Vol. 37, No. 24.
- d. Recommendations for the Safe Handling of Parenteral Antineoplastic Drugs, NIH Publication No. 83-2621.
- e. NIH Guidelines for the Laboratory Use of Chemical Carcinogens, NIH Publication No. 81-2385.

The following materials are also recommended and may be purchased from:

National Academy Press
2102 Constitution Avenue, NW
Washington, DC 20418

- a. Prudent Practices for Handling Hazardous Chemicals in the Laboratory. Price \$19.95
- b. Prudent Practices for the Disposal of Chemicals from the Laboratory. Price \$19.95
- c. Biosafety in the Laboratory: Prudent Practices for Handling and Disposal of Infectious Materials. Price \$19.95

3. Grant applications and contract proposals posing special hazards typically are identified during the initial review process, but such concerns can formally be expressed by agency staff or consultants at any time prior to award. Regardless of the timing of the described concern, grant or contract funding could be delayed until the matter has been resolved to the satisfaction of the awarding component.

Special hazards that are identified after an award is made may lead to suspension of work under the grant or contract pending corrective action by the awardee. (See 45 CFR 74, Subpart M, concerning grant suspension and 48 CFR 12.5 concerning contract "stop work" orders.)

Grantee and contractor organizations are not required to submit documented assurance of their specific attention to the guidelines and standards identified in section 2 of this notice. However, where dictated by the circumstances, grantees and contractors should be able to provide evidence that pertinent health and safety standards have been considered and, where necessary, have been put in practice. Such evidence may be requested by appropriate NIH staff, for example, during a site visit.

POPULATION RESEARCH CENTERS

NIH GUIDE, Volume 23, Number 23, June 17, 1994

RFA AVAILABLE: HD-95-001

P.T. 04; K.W. 0413000, 0413001, 0417000

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: July 1, 1994

Application Receipt Date: October 19, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Demographic and Behavioral Sciences Branch (DBSB), Center for Population Research (CPR), National Institute of Child Health and Human Development (NICHD), announces the availability of an RFA for Population Research Centers. The DBSB supports a number of Population Research Centers, which are designed to provide either integrated groups of research projects and supporting core services (P50) or core services and facilities in support of a large number of active research projects that are supported by a variety of NIH and other funding sources (P30). Two existing center grants are due for competitive renewal in FY 94. This RFA is a solicitation for competition for center grants in this program. Depending on the quality of applications and funding available, DBSB anticipates making two awards.

HEALTHY PEOPLE 2000

The Public Health service is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," the PHS-led national activity for setting priority areas. This RFA, Population Research Centers, is related to the priority areas of family planning, educational and community based programs, maternal and infant health, HIV infection, and immunization and infectious diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government.

MECHANISM OF SUPPORT

The support mechanisms for this program are the Specialized Research Center Grant (P50) and the Center Core Grant (P30). Applications must be consistent with the guidelines governing these two mechanisms. These centers are given a commitment of five years of support that is renewable at five-year intervals. Renewals must be invited by a specific RFA that also will give interested organizations a chance to compete with the incumbent for the award. Because population research center grants are complex entities, it is strongly recommended that interested applicants contact the DBSB staff for a personal consultation regarding the centers program. The current policies and requirements that govern the research grant programs of NIH will prevail (Code of Federal Regulations, Title 42, Part 52 and Title 45, Part 74). The total project period for applications submitted to this RFA is five years. The anticipated award date will be July 1, 1995.

FUNDS AVAILABLE

The DBSB anticipates funding two or three centers in FY 94. \$1,800,000 of first year total cost support has been set aside for this competition, contingent on the availability of funds in the FY 95 appropriation. New P50 applications may not request more than \$600,000 in first year direct cost support. New P30 applications may not request more than \$500,000 in first year, direct cost support and previously funded centers may not request more than 120 percent of the council recommended direct cost level for the final year of the preceding project period. Applications exceeding these budget guidelines will be returned to the applicant unless they receive written permission from NICHD to exceed them. The award of a center is dependent on the receipt of applications of high scientific merit and the availability of funds to support centers.

RESEARCH OBJECTIVES

The DBSB supports research on population dynamics using a variety of approaches found in the social and behavioral sciences. This RFA is specifically designed to stimulate the research community to organize or to maintain population research centers of high quality that will serve as a national research network that fosters communication, innovation and high quality research.

SPECIAL REQUIREMENTS

Applicants should request travel funds to attend an annual meeting of the directors of P50s and P30s in Bethesda, MD.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by July 1, 1994, a letter that includes a brief description of the proposed center, the name, address, and telephone number of the Principal Investigator and the number and title of the RFA in response to which the application may be submitted. The letter of intent is not binding and will not be considered in the review of the application. The sole purpose of the letter of intent is to alert the program staff of the proposed application so that the program may be of assistance in explaining the complex nature of the mechanism.

The letter of intent is to be sent to Dr. V. Jeffery Evans at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used to prepare the application. The type of center grant requested (P30) or (P50) must be indicated on the face page of the application in item #2b. The RFA label available in the form PHS 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for the review. In addition, the RFA title and number must be typed on line 2a of the face page of the application form and the YES box must be marked. The PHS 398 is available from the office of sponsored research at most institutions and can also be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 496-7441.

Applications must be received at the Division of Research Grants by October 19, 1994. If an application is received after that date, it will be returned to the applicant.

REVIEW CONSIDERATIONS

The applications will be reviewed by the Population Research Committee of the NICHD for scientific merit and the NICHD Advisory Council for program relevance and policy issues before awards for meritorious applications are made.

AWARD CRITERIA

The anticipated date of award is July 1, 1995. Funding decisions will be based on the IRG and NACHHD Council recommendations, program relevance, and the availability of funds.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and program guidelines, inquiries regarding programmatic issues, and address the letter of intent to:

V. Jeffery Evans, Ph.D, J.D.
Center for Population Research
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8B13
Bethesda, MD 20892 (U.S. Mail)
Rockville, MD 20852 (Express mail delivery service)
Telephone: (301) 496-1174
FAX: (301) 496-0962

Direct inquiries regarding fiscal matters to:

Ms. Melinda Nelson
Office of Grants and Contracts
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8A17
Bethesda, MD 20892 (U.S. Mail)
Rockville, MD 20852 (Express mail delivery service)
Telephone: (301) 496-5481
FAX: (301) 402-0915

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.864 (Population Research). Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grant policies and Federal Regulations, 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

**5333 Westbard Avenue
Bethesda, MD 20816**



NIH GUIDE

For Grants and Contracts

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National Institutes of Health

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 24
June 24, 1994

RICHARD J. HURRY

* 345189
S135DE

929 WILD FOREST DRIVE
GAITHERSBURG MD 20879 3209

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

THE PUBLIC HEALTH SERVICE (PHS) STRONGLY ENCOURAGES ALL GRANT RECIPIENTS TO PROVIDE A SMOKE-FREE WORKPLACE AND PROMOTE THE NON-USE OF ALL TOBACCO PRODUCTS. THIS IS CONSISTENT WITH THE PHS MISSION TO PROTECT AND ADVANCE THE PHYSICAL AND MENTAL HEALTH OF THE AMERICAN PEOPLE.

UNIFORM BIOLOGICAL MATERIAL TRANSFER AGREEMENT: REQUEST FOR COMMENTS

NIH GUIDE, Volume 23, Number 24, June 24, 1994

P.T. 34; K.W. 1014006

National Institutes of Health

The following is a reprint of the Uniform Biological Material Transfer Agreement: Request for Comments, which was published in the Federal Register of June 21, 1994 (59 FR 32000).

AGENCY: National Institutes of Health (NIH), Public Health Service, DHHS

BACKGROUND: Open access to the results of federally-funded research is a cornerstone of NIH's research policy. In the case of many research projects, this includes not only access to information as can be provided in publications, but also access to biological research materials necessary to replicate or build on the initial results. Frequently, the exchange of research materials between scientists and separate institutions involves case-by-case negotiation of material transfer agreements (MTAs). In order to guide and facilitate the increasing number of such transfers, the Public Health Service (PHS) issued in 1988, a "Policy Relating to Distribution of Unique Research Resources Produced with PHS Funding" (NIH GUIDE FOR GRANTS AND CONTRACTS, Vol. 17, No. 29, September 16, 1988: pg. 1), that was followed in 1989 by adoption of a standard Material Transfer Agreement form for use by NIH scientists. Such agreements are important because they require the recipient to use care in the handling of the materials, to maintain control over the distribution of the materials, to acknowledge the provider in publications, and to follow relevant Public Health Service (PHS) guidelines relating to recombinant DNA, human subjects research, use of animals, etc. However, while most institutions have adopted some standard material transfer agreement form, they are not all consistent.

ISSUE: Several concerns have affected the sharing of research materials. These include delays in sharing of materials while conducting negotiations on individual MTAs, required grants of invention rights to improvements to the materials or to inventions made using the materials, and required approval prior to publication. Such problems have resulted in significant delays in sharing materials, undue administrative barriers to sharing, and in some cases, lack of availability of materials for further research by federal grantees. (For reports and discussion of these issues, please refer to THE NEW BIOLOGIST, Vol. 2, No. 6, June 1990: pp 495-497; and SCIENCE, Vol. 248, 25 May, 1990: pp 952-957).

In addition, there is a desire to have a uniform agreement for the sharing of non-proprietary materials.

PROPOSAL: The NIH, in participation with representatives of academia and industry, has coordinated the development of a proposed uniform biological material transfer agreement (UBMTA) to address concerns about contractual obligations imposed by some MTAs and to simplify the process of sharing PROPRIETARY materials between non-profit institutions. The Association of University Technology Managers, particularly Ms. Joyce Brinton, Harvard University; Ms. Lita Nelsen, Massachusetts Institute of Technology; and Dr. Sandra Shotwell, Oregon Health Sciences University, have played leadership roles in furthering the development of common materials sharing practices. The consistent use of this agreement by grantee institutions could reduce the administrative burden of sharing materials as investigators come to rely on common acceptance of the terms of the UBMTA by cooperating institutions.

The NIH proposes that the UBMTA be considered for general use in the exchange of materials for research purposes between non-profit institutions. While use of the UBMTA may not be appropriate for every material transfer, if used for the majority of transfers, it could set standards for materials sharing that would be of long term benefit to the research enterprise and to the public health.

As a further suggestion to simplify the process of materials sharing, it is proposed that the UBMTA be approved at the institutional level, and handled in a treaty format, so that individual transfers could be made with reference to the UBMTA, without the need for separate negotiation of an individual document to cover each transfer. As a result, transfers of biological materials would be accomplished by an implementing letter (see sample) containing a description of the material, a statement indicating that the material was being transferred in accordance with the terms of the UBMTA and signed by the PROVIDER SCIENTIST and the RECIPIENT SCIENTIST. Thus, sharing of materials between institutions, each of which had signed the UBMTA, would be significantly simplified. At the same time, any institution would retain the option to handle a specific material on a customized basis, i.e., the use of the UBMTA would not be mandatory, even for signatory institutions.

For non-proprietary materials, a Simple Letter Agreement has also been developed, which incorporates many of the same principles as the UBMTA. This Letter Agreement could be used where the institutions have not agreed to the UBMTA.

The full text of the treaty version of the UBMTA, the implementing letter, and a simple one-page letter agreement for non-proprietary material follows. The NIH welcomes public comment on the documents themselves, as well as their proposed use. Comments should be addressed to: UBMTA Project, c/o Office of Technology Transfer, Box 13, 6011 Executive Boulevard, Rockville, MD 20852-3804. Comments may also be sent by facsimile transmission to: UBMTA Project at (301) 402-0220.

DATE: Comments must be received by NIH on or before July 21, 1994.

MASTER AGREEMENT
REGARDING USE OF THE
UNIFORM BIOLOGICAL MATERIAL TRANSFER AGREEMENT (UBMTA)
FOR EXCHANGES OF BIOLOGICAL MATERIAL BETWEEN
NON-PROFIT INSTITUTIONS

Upon execution of an Implementing Letter in the form attached which specifies the materials to be transferred, this institution agrees to be bound by the terms of the Non-Profit to Non-Profit UBMTA, dated ----- also attached.

Enclosures: Implementing Letter format
UBMTA

Institution:

Address:

Authorized Official:

Title:

Signature:

Date:

Sample UBMTA Implementing Letter

Definitions:

PROVIDER: Institution providing the Original Material (Enter name and address here):

Provider's Scientist (Enter name and address here):

RECIPIENT: Institution receiving the Original Material (Enter name and address here):

Recipient's Scientist (Enter name and address here):

Original Material (Enter description):

PROVIDER has filed patent applications claiming the MATERIAL or uses thereof:

Yes No

If PROVIDER has granted any rights to a third party (other than the customary rights granted to the federal government or non-profit foundations) which would affect RECIPIENT, those rights are specified below:

Termination date for this letter (if any is to be specified):

The parties executing this Implementing Letter agree to be bound by the terms of the Non-Profit to Non-Profit UBMTA for the transfer specified above:

AGREED:

PROVIDER

Institution:

Address:

Provider Scientist

Name:

Title:

Signature:

Date:

RECIPIENT

Institution:

Address:

Recipient Scientist

Name:

Title:

Signature:

Date:

Certification: I hereby certify that the RECIPIENT institution has accepted and signed an unmodified copy of the date version of the Uniform Biological Material Transfer Agreement (UBMTA) developed in cooperation with the National Institutes of Health.

RECIPIENT'S INSTITUTIONAL CERTIFICATION

(Authorized signature)

(Date)

NON-PROFIT TO NON-PROFIT
UNIFORM BIOLOGICAL MATERIAL TRANSFER AGREEMENT
(DATE) - TREATY VERSION
DEVELOPED IN COOPERATION WITH THE NATIONAL INSTITUTES OF HEALTH

Definitions:

PROVIDER: Institution providing the Original Material. (Name and address to be specified in an implementing letter)

Provider's Scientist: (Name and address to be specified in an implementing letter)

RECIPIENT: Institution receiving the Original Material. (Name and address to be specified in an implementing letter)

Recipient's Scientist: (Name and address to be specified in an implementing letter)

Original Material: (Description to be specified in an implementing letter)

MATERIAL: Original Material plus Progeny and Unmodified Derivatives. The MATERIAL shall not include: (i) Modifications or (ii) other substances created by the RECIPIENT through the use of the MATERIAL which are not Progeny or Unmodified Derivatives.

Progeny: Unmodified descendant from the MATERIAL, such as virus from virus, cell from cell, or organism from organism.

Unmodified Derivatives: Substances created by RECIPIENT which constitute an unmodified functional sub-unit or an expression product of the Original Material. Some examples include: subclones of unmodified cell lines, purified or fractionated sub-sets of the Original Material, proteins expressed by DNA/RNA supplied by PROVIDER, monoclonal antibodies secreted by a hybridoma cell line, sub-sets of the Original Material such as novel plasmids or vectors.

Modifications: Substances created by RECIPIENT which contain/incorporate the MATERIAL (Original Material, Progeny or Unmodified Derivatives).

Terms and Conditions of this Agreement:

1. The MATERIAL is the property of PROVIDER and is to be used by RECIPIENT solely for research purposes at RECIPIENT's institution and only under the direction of the Recipient's Scientist. The MATERIAL will not be used in human subjects or in clinical trials involving human subjects without the written permission of PROVIDER. Patent applications claiming the MATERIAL or uses thereof to be specified in an implementing letter.

2. The Recipient's Scientist agrees not to transfer the MATERIAL to anyone who does not work under his or her direct supervision at RECIPIENT's institution without the prior written consent of PROVIDER. Recipient's Scientist shall refer any request for the MATERIAL to PROVIDER. To the extent supplies are available, PROVIDER or Provider's Scientist agrees to make the MATERIAL available under a UBMTA to other scientists (at least those at non-profit or governmental institutions) who wish to replicate Recipient's Scientist's research.

3. (a) RECIPIENT shall have the right, without restriction to distribute substances created by RECIPIENT through the use of the MATERIAL only if those substances are not Progeny, Unmodified Derivatives, or Modifications.

(b) Upon notice to PROVIDER and under a UBMTA (or an agreement at least as protective of PROVIDER's rights), RECIPIENT may distribute Modifications to non-profit or governmental organizations for research purposes only.

(c) Upon written permission from PROVIDER, RECIPIENT may distribute Modifications for commercial use. It is recognized by RECIPIENT that such commercial use may require a commercial license from PROVIDER and PROVIDER has no obligation to grant such a commercial license. Nothing in this paragraph, however, shall prevent RECIPIENT from granting commercial licenses under RECIPIENT's patent rights claiming such Modifications.

4. (a) Ownership of tangible property as between PROVIDER and RECIPIENT is defined in Attachment A.

(b) RECIPIENT is free to file patent applications claiming inventions made by RECIPIENT through the use of the MATERIAL but agrees to notify PROVIDER upon filing a patent application claiming Modifications or uses of the MATERIAL.

5. (a) Except as expressly provided in this Agreement, no rights are provided to RECIPIENT under any patents, patent applications, trade secrets or other proprietary rights of PROVIDER. In particular, no rights are provided to use the MATERIAL or Modifications and any related patents of PROVIDER for profit-making or commercial purposes, such as sale of the MATERIAL or Modifications, use in manufacturing, provision of a service to a third party in exchange for consideration (not including sponsored research activities except as provided for in 5(b)).

(b) If RECIPIENT desires to use the MATERIAL or Modifications for such profit-making or commercial purposes, RECIPIENT agrees, in advance of such use, to negotiate in good faith with PROVIDER to establish the terms of a commercial license. It is understood by RECIPIENT that PROVIDER shall have no obligation to grant such a license to RECIPIENT, and may grant exclusive or non-exclusive commercial licenses to others.

6. The provision of the MATERIAL to RECIPIENT shall not alter any pre-existing right to the MATERIAL. If PROVIDER has granted any rights to a third party (other than the customary rights granted to the Federal Government or non-profit foundations) which would affect RECIPIENT, those rights will be identified by PROVIDER in an implementing letter.

7. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

8. Except to the extent prohibited by law, RECIPIENT assumes all liability for damages which may arise from its use, storage or disposal of the MATERIAL. PROVIDER will not be liable to RECIPIENT for any loss, claim or demand made by RECIPIENT, or made against RECIPIENT by any other party, due to or arising from the use of the MATERIAL by RECIPIENT, except to the extent permitted by law when caused by the gross negligence or willful misconduct of PROVIDER.

9. This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the MATERIAL or Modifications. Recipient's Scientist agrees to provide appropriate acknowledgement of the source of the MATERIAL in all publications.

10. RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations, including Public Health Service and NIH regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA.

11. (a) This Agreement will terminate on the earliest of the following dates: (1) when the MATERIAL becomes generally available from third parties, for example, through reagent catalogs or public depositories, or (2) on completion of RECIPIENT's current research with the MATERIAL, or (3) on thirty (30) days written notice by either party to the other, or (4) on the date specified in an implementing letter. Paragraphs 7 and 8 shall survive termination.

(b) If termination should occur under 11 (a)(1), RECIPIENT shall be bound to the PROVIDER by the least restrictive terms applicable to MATERIAL obtained from the then-available sources.

(c) Except as provided in 11. (d) below, on termination of this Agreement under 11. (a)(2), (3), or (4) above, RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of PROVIDER, return or destroy any remaining MATERIAL. RECIPIENT will also either destroy Modifications or remain bound by the terms of paragraphs 4 and 5 as they apply to Modifications.

(d) In the event PROVIDER terminates this Agreement under 11.(a)(3) other than for breach of this Agreement or with cause such as an imminent health risk or patent infringement, PROVIDER will defer the effective date of termination for a period of up to one year, upon request from RECIPIENT, to permit completion of research in progress.

12. The MATERIAL is provided free or with a fee solely to reimburse PROVIDER for its distribution costs. If a fee is requested, it will be enumerated in an implementing letter.

Belonging to PROVIDER

MATERIAL

Original Material

Progeny

Unmodified Derivatives

Belonging to RECIPIENT*

Modifications (however, PROVIDER retains ownership rights to any form of the MATERIAL included therein)

Those substances created through the use of the MATERIAL or Modifications, but which are not Progeny, Unmodified Derivatives or Modifications (e.g., do not contain the Original Material or Unmodified Derivatives).

* If resulting from the collaborative efforts of PROVIDER and RECIPIENT, joint ownership may be negotiated.

SIMPLE LETTER AGREEMENT FOR TRANSFER OF NON-PROPRIETARY
BIOLOGICAL MATERIAL FROM NON-PROFIT TO NON-PROFIT

TO:
Address:

(RECIPIENT)

FROM:
Address:

(PROVIDER)

Re: Biological Material Identified as:

In response to RECIPIENT's request for the above-identified Biological Material, PROVIDER's institution asks that RECIPIENT and Recipient's Scientist agree to the following before RECIPIENT receives the Biological Material:

1. The above Biological Material is the property of PROVIDER and is made available as a service to the research community.
2. The Biological Material will be used for research purposes only.
3. The Biological Material will not be further distributed to others without PROVIDER's written permission; except such permission is not required where RECIPIENT agrees, upon request, to provide the Biological Material (subject to its availability) or enabling information to appropriate investigators solely for the purpose of replicating or verifying RECIPIENT'S research.
4. RECIPIENT agrees to acknowledge the source of the Biological Material in any publications reporting use of it.
5. The Biological Material is experimental in nature and IT IS PROVIDED WITHOUT ANY WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. RECIPIENT and Recipient's Scientist agree to assume all liability for damages which arise from use, storage or disposal of the Biological Material.
6. RECIPIENT agrees to use Biological Material in compliance with all applicable statutes and regulations, including, for example, those relating to research involving the use of human and animal subjects or recombinant DNA.

RECIPIENT and Recipient's Scientist should sign both copies of this letter and return one signed copy to PROVIDER. PROVIDER will then forward the Biological Materials.

PROVIDER

RECIPIENT'S SCIENTIST

(signature)

(date)

(signature)

(date)

RECIPIENT INSTITUTIONAL APPROVAL

(authorized signature)

(date)

Name:
Title:
Address:

AIDS CLINICAL TRIALS GROUP MEETING

NIH GUIDE, Volume 23, Number 24, June 24, 1994

P.T. 42; K.W. 0715008, 0755015

National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID) anticipates the release of a Request for Applications this summer for the formation of AIDS Clinical Trials Group(s) (ACTG). The cooperative group(s) will conduct Phase I, II, and III adult clinical trials to evaluate interventions for the treatment of HIV infection, AIDS, and opportunistic diseases resulting from HIV-associated immunosuppression. The current ACTG awardees and NIAID staff will hold a scientific and planning meeting in Washington, DC, July 23-27, 1994. Potential applicants are invited to attend the meeting to gain an understanding of the current research agenda and organizational structure of the ACTG.

INQUIRIES

For further information concerning the meeting and registration contact:

Rii Conference Department
P.O. Box 13433
Silver Spring, MD 20911-0433
Telephone: (301) 565-404

Individuals who are unable to attend the meeting may obtain the agenda from:

Sheri Bernstein
Division of AIDS
National Institute of Allergy and Infectious Diseases
Bethesda, MD 20892
Telephone: (301) 496-8215

NOTICES OF AVAILABILITY (RFPs AND RFAs)

SYNTHESIS AND DEVELOPMENT OF NEW SPERMICIDES WITH MICROBICIDAL PROPERTIES

NIH GUIDE, Volume 23, Number 24, June 24, 1994

RFP AVAILABLE: NICHD-CD-94-14

P.T. 34; K.W. 0750020, 1002027, 1003012, 1003006

National Institute of Child Health and Human Development

The Contraceptive Development Branch of the Center for Population Research, National Institute of Child Health and Human Development, is interested in stimulating investigations into the synthesis, testing, and development of novel spermicidal\anti-STD agents that inactivate human sperm and sexually transmitted disease (STD) pathogens, especially HIV, preferably via mechanisms other than the disruption of cell membranes. The spermicidal\anti-STD agent is defined as (1) an agent comprised of a single chemical entity possessing both spermicidal and anti-STD activity or (2) an agent that is comprised of two chemical entities, one possessing spermicidal activity and the other anti-STD activity. The goals are to obtain human spermicidal\anti-STD agents that (a) are equipotent with or more potent than nonoxynol-9 (N-9), (b) have a rapid onset of sperm inactivation equivalent to or greater than that of N-9, (c) do not cause vaginal irritation, (d) can inactivate STD pathogens while producing only a transient effect on normal human vaginal flora, (e) are miscible with human cervical mucus, (f) are inexpensive, and (g) are aesthetically pleasing (i.e., colorless, odorless). Such investigations will involve the synthesis and biological evaluation of the spermicidal\anti-STD agents by the contractor.

This project requires both the expertise of a Ph.D. synthetic organic or medicinal chemist and a Ph.D. biologist. A collaborative effort (in-house or via subcontract arrangement) of such scientists is essential for the success of the project. Organizations must have adequate facilities to carry out the proposed syntheses and biological testing. The Government estimates the effort to be approximately 4.0 technical person-years annually. The principal investigator or co-principal investigators should devote approximately 20 percent effort to this project.

All responsible sources may submit a proposal that will be considered by the agency. It is anticipated that five cost-reimbursement incrementally funded type contracts will be awarded as a result of the Request for Proposals (RFP) for a period of 36 months, beginning April 3, 1995. This announcement is not an RFP. RFP No. NICHD-CD-94-14 will be available on or about June 30, 1994. Proposals will be due approximately 90 days thereafter.

INQUIRIES

Requests for the RFP must cite the above RFP number. Copies of the RFP may be obtained by sending a written or FAX request to:

Paul J. Duska
Office of Grants and Contracts
National Institute of Child Health and Human Development
6100 Building, Suite 7A-07
Bethesda, MD 20892
FAX: (301) 402-3676

SPECIALIZED PROGRAMS OF RESEARCH EXCELLENCE IN BREAST CANCER

NIH GUIDE, Volume 23, Number 24, June 24, 1994

RFA AVAILABLE: CA-94-027

P.T. 34; K.W. 0715036, 0710030, 0745020, 0745027, 0745070

National Cancer Institute

Letter of Intent Receipt Date: July 29, 1994

Application Receipt Date: October 25, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES" BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Organ Systems Coordinating Branch of the Division of Cancer Biology, Diagnosis and Centers (DCBDC) at the National Cancer Institute (NCI) invites grant applications for Specialized Programs of Research Excellence (SPORE) in Breast Cancer. The intent of this initiative is to expand the Breast Cancer SPORes from the current four SPORes to a minimum of five SPORes through open competition by making awards to those institutions that can conduct the highest quality balanced translational research approaches on the prevention, etiology, screening, diagnosis, and treatment of breast cancer. SPORes are at institutions that have made or will make a strong institutional commitment to the organization and conduct of these programs. SPORE applicants will be judged on their current and potential ability to translate basic research findings into innovative research settings involving patients and populations. Each SPORE is encouraged to conduct rehabilitation and quality-of-life research. Each SPORE must provide career development opportunities for new and established investigators who wish to pursue active research careers in translational breast cancer research; develop and maintain human breast cancer tissue resources that will benefit translational research; develop extended collaborations in critical areas of research need with laboratory scientists and clinical scientists within the institution and in other institutions; and participate with other SPORes on a regular basis to share positive and negative information, assess scientific progress in the field, identify new research opportunities, and promote inter-SPORE collaborations to resolve areas of scientific controversy. Each SPORE and the "network" of SPORes is expected to conduct research that will have the most immediate impact possible on reducing incidence and mortality to human breast cancer.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Specialized Program of Research Excellence (SPORE) in Breast Cancer, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. To be eligible, applicant organizations must have (1) a minimum of three independent investigators who are successful in obtaining peer-reviewed research support directly related to breast cancer, and who together represent experience in both laboratory and clinical research, or in the alternate, a minimum of three independent investigators, each having published articles that significantly address breast cancer in peer-reviewed research journals, and who, as a group, represent experience in both laboratory and clinical research; (2) access to a patient care and service facility that serves breast cancer patients and, if the facility is not part of the parent institution, a statement that assures access to breast cancer patients for clinical research; the statement must be signed by the responsible officials of the applicant institution and the consortial care facility; (3) although applications must be submitted from a single institution, they may include subcontracted collaborative scientific arrangements with scientists from other institutions as long as these arrangements are clearly delineated, and formally and officially confirmed by signed statements from the responsible officials of each institution. However, a full institutional commitment must come from the parent institution receiving the award.

MECHANISM OF SUPPORT

Support of this program will be through the specialized center grant (P50) mechanism. Applicants will be responsible for the planning, direction, and execution of the proposed SPORE program. Except as otherwise noted in this RFA, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement.

This RFA is a one-time solicitation. The total project period for competing P50 renewal SPORE applications may not exceed five years; new applicants or applicants that have received P20 SPORE feasibility awards in the past may request up to three years of support. All new and competing renewal P50 SPORE applications may request a maximum annual direct cost of \$1.5 million and maximum annual total cost of \$2.5 million per individual SPORE. The earliest anticipated award date is September 1, 1995.

FUNDS AVAILABLE

The NCI anticipates making at least five awards and anticipates setting aside \$2.5 million per award or \$12.5 million total for the initial year's funding. Funding in response to this RFA is dependent upon the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of NCI, the award of grants pursuant to this RFA is contingent upon the anticipated availability of funds for this purpose.

RESEARCH OBJECTIVES

The goal of this RFA is to expand the current Breast Cancer SPORE program with the addition of at least one new SPORE. Each SPORE assembles critical masses of laboratory and clinical scientists to work together on human breast cancer and to focus on innovative translation of basic findings into research settings involving patients and populations. The ultimate objective is to reduce incidence and mortality, and to increase and improve survival to the disease. The essential characteristics of a SPORE include (1) a strong scientific program that will have a clear impact on the human disease, (2) a strong innovative developmental or pilot research program that can respond quickly to new research opportunities, (3) a strong career development program to develop and expand the scientific cadre of investigators dedicated to translational research on human breast cancer, (4) a human breast cancer tissue procurement resource and other resources specifically dedicated to translational research objectives, and (5) a willingness and commitment to work with other SPOREs and scientists in order to maximize research progress.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by July 29, 1994, a letter of intent that includes the name and address of the principal investigator and identifies the component research projects, core units and their principal investigators, any collaborating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding and does not enter into the review of subsequent applications, it provides an indication of the number and scope of the applications to be reviewed. Furthermore, NCI staff can discuss the most recent policies of the NCI relative to funding issues, potential problems in meeting eligibility requirements or clarification of the peer review process before the final application is submitted.

The letter of intent is to be sent to Dr. Andrew Chiarodo at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Complete applications are due no later than October 25, 1994. Applications received after this date will not be accepted. The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone: (301) 594-7248; and from the NCI Program Director listed under INQUIRIES.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed initially by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to this RFA is an NCI program staff function. Applications judged to be non-responsive will be returned without review. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit and for special SPORE characteristics and requirements as described in the complete RFA. Questions concerning the responsiveness of proposed programs to the RFA may be directed to program staff listed under INQUIRIES.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Andrew Chiarodo, Ph.D.
Division of Cancer Biology, Diagnosis, and Centers
National Cancer Institute
6130 Executive Boulevard
Executive Plaza North, Suite 512
Bethesda, MD 20852
Telephone: (301) 496-8528

Direct inquiries regarding fiscal matters to:

Joan Metcalfe
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800 ext. 228

AUTHORITY AND REGULATIONS

This program is described in the catalog of Federal Domestic Assistance no. 13.397. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410 as amended: 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

THE MECHANISMS OF EMBRYONIC/FETAL-MATERNAL TOLERANCE

NIH GUIDE, Volume 23, Number 24, June 24, 1994

RFA AVAILABLE: AI-94-023

P.T. 34; K.W. 0705048, 0413002, 0775020, 0710065

National Institute of Allergy and Infectious Diseases
National Institute of Child Health and Human Development
Office of Research on Women's Health

Letter of Intent Receipt Date: August 15, 1994
Application Receipt Date: November 16, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACTS LISTED IN "INQUIRIES" BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Allergy, Immunology, and Transplantation of the National Institute of Allergy and Infectious Diseases (NIAID); the Developmental Biology, Genetics, and Teratology Branch, Center for Research for Mothers and Children, and the Reproductive Sciences Branch, Center for Population Research, of the National Institute of Child Health and Human Development (NICHD); and the Office of Research on Women's Health (ORWH) of the Office of the NIH Director invite applications for basic studies designed to identify the underlying immunologic and/or genetic mechanism(s) that protect the embryo and fetus from maternal rejection and to elucidate the interactions of the fetal and maternal immune systems in successful pregnancy. Despite genetic differences known to elicit strong immunologic responses under other circumstances, i.e., Major Histocompatibility Complex (MHC) disparities, mothers do not reject their semiallogeneic embryos or fetuses. This remarkable immunologic accommodation is undoubtedly due to many finely orchestrated events. The goal of this initiative is to promote research that will advance our understanding of the underlying mechanisms of this unique form of immunologic tolerance and lead to improved clinical applications.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, The Mechanisms of Embryonic/Fetal-Maternal Tolerance, is related to the priority areas of immunization and infectious diseases, family planning, and maternal and infant health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone (202) 782-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private institutions, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible to apply for First Independent Research Support and Transition (FIRST) (R29) Awards. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The mechanisms of support will be the individual research project grant (R01) and the FIRST (R29) grant. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period may not exceed five years; foreign awards may not exceed three years.

FUNDS AVAILABLE

The estimated funds available for the total (direct and indirect) first year costs of all awards made under this RFA will be \$2,000,000. In Fiscal Year 1995, the NIAID and the ORWH plan to provide up to \$1,000,000 to fund up to five R01/R29s and the NICHD plans to provide up to \$1,000,000 to fund up to six R01s/R29s. The usual PHS policies governing grants administration and management will apply. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NIAID, the NICHD, and the ORWH, awards pursuant to this RFA are contingent upon the availability of funds for this purpose. Funding beyond the first and subsequent years of the grant will be contingent upon satisfactory progress during the preceding years and availability of funds.

RESEARCH OBJECTIVES

The objective of this RFA is to support innovative research designed to apply current research technologies and scientific advances to facilitate the identification of mechanisms that protect the embryo and fetus from maternal immunologic rejection as well as the elucidation of embryonic/fetal-maternal immune interactions. Suitable models of study may include in vitro and in vivo animal models, transgenic animal models, and human studies (preclinical or clinical).

Relevant topics of research include, but are not limited to, the following:

- o The role of MHC in embryonic/fetal-maternal tolerance, including:
 - a. identification of regulatory mechanisms (transcription, translation and post-translational modifications) of MHC genes and functional expression, lack of expression, or repression on embryonic/fetal tissues as they relate to immune

function;

b. differential MHC expression and the kinetics of this expression; and

c. identification of unique MHC molecule(s) involved in embryonic/fetal accommodation and elucidation of the mechanisms of this accommodation.

o Studies of the expression and function of unique cell surface molecules (non-MHC molecules), which may play a role in embryonic/fetal protection.

o The gene regulation and differential expression of cytokines and their receptors (soluble or membrane-bound) and the role this expression has on embryonic/fetal tolerance and successful pregnancy.

o The role of immune cells in embryonic/fetal maternal tolerance, including:

a. identification of immune cell populations that have a regulatory role in embryonic/fetal tolerance and characterization of their effector function(s); and

b. delineation of the function(s) of immune cells found in the pregnant uterus and/or placenta which ensures a tolerant environment, e.g., altered antigen-processing/presentation ability of antigen presenting cells.

o Interaction of the endocrine and immune system as it pertains to the induction and maintenance of embryonic/fetal-maternal tolerance.

NOTE: Studies may address any post-fertilization influencing immunologic events. Studies of infectious disease as it relates to the regulation - or dysregulation - of embryonic/fetal-maternal tolerance are within the scope of this RFA with the exception of sexually transmitted diseases (STDs) and the Human Immunodeficiency Virus (HIV). Also, the development of treatments for infertility or miscarriages; and contraception development are not within the scope of this RFA.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by August 15, 1994, a letter of intent that includes a descriptive title of the overall proposed research, the name, address and telephone number of the Principal Investigator, and the number and title of this RFA. Although the letter of intent is not required, is not binding, does not commit the sender to submit an application, and does not enter into the review of subsequent applications, the information that it contains allows NIH staff to estimate the potential review workload and to avoid conflict of interest in the review. The letter of intent is to be sent to Dr. Allan Lock at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted on the standard research grant application form PHS 398 (rev. 09/91). These application forms may be obtained from the institution's office for sponsored research or its equivalent and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

Applications must be received by November 16, 1994. For purposes of identification and processing, item 2a on the face page of the application must be marked "YES" and the RFA number and the words "THE MECHANISMS OF EMBRYONIC/FETAL-MATERNAL TOLERANCE" must be typed in.

REVIEW CONSIDERATIONS

The general criteria for applications are the review criteria used for traditional research project grant applications.

AWARD CRITERIA

Funding decisions will be made on the basis of scientific and technical merit as determined by peer review, program priorities, and the availability of funds.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA and the NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research, as well as inquiries regarding programmatic issues to:

M. Michele Hogan, Ph.D.
Division of Allergy, Immunology and Transplantation
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4A21
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7551
FAX: (301) 402-2571

Allan Lock, D.V.M.
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
Building 61E, Room 4B01
6100 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-5541
FAX: (301) 402-4083

Address the letter of intent to Dr. Allan Lock.

Direct inquiries regarding review issues and mail two copies of the application and all five sets of appendices to:

Olivia T. Preble, Ph.D.
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C20
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-8208
FAX: (301) 402-2638

Direct inquiries regarding fiscal matters to:

Ms. Cynthia R. McDermott
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B22
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7075

Mr. E. Douglas Shawver
Office of Grants and Contracts
National Institute of Child Health and Human Development
Building 61E, Room 8A17K
6100 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-1303

Schedule

Letter of Intent Receipt Date:	August 15, 1994
Application Receipt Date:	November 16, 1994
Scientific Review Date:	February 1995
Advisory Council Date:	June 1995
Earliest Award Date:	August 1995

AUTHORITY AND REGULATIONS

The NIAID program is described in the Catalog of Federal Domestic Assistance, No. 93.855 - Immunology, Allergy and Transplantation Research; and the NICHD program in No. 93.864 - Population Research and No. 93.865 - Research for Mothers and Children. Awards for NIAID will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations 45 CFR Part 74 and 92. Awards for NICHD are made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NIH GUIDE, Volume 23, Number 24, June 24, 1994

RFA AVAILABLE: HD-95-002

P.T. 34; K.W. 0413000, 0725000

National Institute of Child Health and Human Development
National Institute of Environmental Health Sciences

Application Receipt Date: November 17, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Demographic and Behavioral Sciences Branch (DBSB) of the National Institute of Child Health and Human Development (NICHD) and the National Institute of Environmental Health Sciences (NIEHS) invite applications investigating the interrelationship between population change and the environment. Population change manifests itself in many ways such as changes in the size, distribution and characteristics of the overall population and changes in key components of change such as fertility, migration, mortality, and household structure. For purposes of this RFA, the environment should be limited to considerations most easily related to population change such as land use, flora and fauna, soil and water quality. It is clear that population change and the environment are interrelated in many complicated ways throughout the world and the relationship is modulated by socio-economic and public policy influences. The goal of this RFA is to establish a broad foundation of demographic/environmental research in a variety of physical settings worldwide.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Population and the Environment, is related to the priority areas of family and child health and environmental health sciences. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-004734-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications for R01s may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications from minorities, women and disabled persons are encouraged. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards.

MECHANISM OF SUPPORT

Applications in response to this RFA will be funded through the individual research project grant (R01) and the FIRST (R29) awards. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for an application submitted in response to the present RFA may not exceed five years. This RFA is for a single competition with the application receipt deadline of November 17, 1994. Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of an award will vary also. For R29 applications, the budgetary conventions governing FIRST awards will apply.

FUNDS AVAILABLE

The NICHD has set aside \$1,000,000 direct costs for the first year of support for the program. It is anticipated that five to ten awards will be made depending on the nature and scope of the projects.

The NIEHS has set aside \$250,000 of total cost support in the first year of the program and these funds may be used to fund additional projects or co-fund projects with NICHD. The NIEHS has special interest in supporting research in the "border zone" between the United States and Mexico.

It is anticipated that only new applications will be received. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of NICHD and NIEHS, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

This RFA encourages three types of studies: (1) studies of the effect of population change on the environment, (2) studies of the effect of environmental change on factors such as fertility, mortality, migration, and distribution that determine population change, and (3) studies of the reciprocal influences of population and environmental change. Investigators are free to formulate studies that are relevant to any of the above mentioned types, and because this is an emerging area of science, investigators are encouraged to propose feasible studies that exploit existing research opportunities with rigor and lay the foundations for future progress.

Environmental impact should be limited to considerations most easily related to population change such as land use, flora and fauna, soil and water quality. Population change manifests itself in many ways such as changes in the size, distribution and characteristics of the overall population and changes in key components of change like fertility, migration, mortality, and household structure. It is clear that population change and the environment are interrelated

in many complicated ways throughout the world and the relationship is modulated by socio-economic and public policy influences, and investigators are encouraged to account for them. Since much of the scientific debate is about whether population change or consumption and other aspects of human behavior are primarily responsible for environmental change, effort should be made to resolve this debate. The goal of this RFA is to establish a broad foundation of demographic/environmental research in a variety of physical settings worldwide. Each project should contain a strong element of population research that extends to include environmental considerations. Because this is an emerging area of research, pilot projects and methodological projects are encouraged.

SPECIAL REQUIREMENTS

Annual meetings will be held to foster the sharing of information, data, and other experiences. Principal and co-investigators will be encouraged to attend these meetings, and funds may be included in the application budget for one two-day meeting per year in Bethesda, Maryland to discuss the research with other investigators. Investigators may propose the creation and maintenance of a LISTSERV discussion group that would facilitate communication within the group of successful grantees and other interested parties. Costs for this should be detailed in the budget and the operating parameters should be discussed in the budget notes. If more than one investigator proposes this service then DBSB will choose to fund only one.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91) that is available in most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. FIRST (R29) award applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST (R29) award applications submitted without the required number of reference letters will be considered incomplete and will be returned without review. Applications must be identified by checking the "YES" box in Item 2a on the face page of the application and by typing the words, "In Response to RFA HD-95-002." The RFA label in form PHS 398 must be affixed to the bottom of the face page of the original application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. Applications must be received by November 17, 1994. Late applications will not be accepted. The signed original and three copies of the applications must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

The applications will be reviewed for scientific merit by a Special Review Committee convened by NICHD and the appropriate Institute's Advisory Council for program relevance and policy issues before awards for meritorious applications are made.

AWARD CRITERIA

The anticipated date of award is July 1, 1995. Scientific merit and technical proficiency, as described in the application, will be the predominant criteria for determining funding. Also, the degree to which interdisciplinary research is incorporated into a sound demographic research design will be taken into account in funding decisions.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

V. Jeffery Evans, Ph.D., J.D.
Center for Population Research
National Institute of Child Health and Human Development
Building 6100, Room 8813
Bethesda, MD 20892
Telephone: (301) 496-1174
FAX: (301) 496-0962
Internet: EVANSJ@HD01.NICHD.NIH.GOV

Gwen Collman, Ph.D.
Chemical Exposures and Molecular Biology Branch
National Institute of Environmental Health Sciences
Building 3, Room 308
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-4980
FAX: (919) 541-2843

Direct Inquiries regarding fiscal matters to:

Ms. Melinda Nelson
Office of Grants and Contracts
National Institute of Child Health and Human Development
Building 6100, Room 8A17
Bethesda, MD 20892
Telephone: (301) 496-5481
FAX: (301) 402-0915

David L. Mineo
Grants Management Branch
National Institute of Environmental Health Sciences
Building 3, Room 2038
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-7628

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.864 (Population Research). Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations, 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372, or to Health Systems Agency Review.

VASCULAR DISEASE ACADEMIC AWARD

NIH GUIDE, Volume 23, Number 24, June 24, 1994

RFA AVAILABLE: HL-94-015

P.T. 34; K.W. 0715040

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: November 30, 1994

Application Receipt Date: January 10, 1995

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACTS LISTED BELOW IN "INQUIRIES." FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) announces the fourth competition for Vascular Disease Academic Awards. These awards have the dual purpose of encouraging the development and/or improving the quality of clinical, educational, and research programs in vascular disease and of encouraging the professional development of the awardee so that he or she can serve as the focal point for multidisciplinary interactions in the field of vascular medicine.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Vascular Disease Academic Award, is related to the priority areas of heart disease and stroke and chronic disabling diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202 783-3238).

ELIGIBILITY REQUIREMENTS

Each School of Medicine or Osteopathy in the United States and its possessions and territories is eligible to compete for a nonrenewable Vascular Disease Academic Award for a project period that does not exceed five years. Awards will not be made to foreign institutions nor to domestic applicants with international components. The Principal Investigator must hold the M.D. or D.O. degree or the equivalent. Applications from minority individuals and women are encouraged. An individual institution may submit one application only for a given receipt date. Institutions that have already received a Vascular Disease Academic Award may not apply for a further award.

MECHANISM OF SUPPORT

The mechanism of support for this program is the Academic/Teacher Award (K07).

FUNDS AVAILABLE

Applicants for a systemic or a pulmonary vascular program may request up to \$100,000 in direct costs for the first year and applicants for a combined systemic and pulmonary vascular program may request up to \$125,000 direct costs for the first year, with a four percent increase in each additional year. Award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. It is anticipated that no more than a total of five awards will be made in

RESEARCH OBJECTIVES

This Academic Award was initiated to address problems that prevent rapid and effective application of new developments in medical diagnosis and management of the individual patient with vascular disease. The purpose of this award is to provide financial support for individuals in conjunction with their institutions, to develop and implement approaches to the coordinated care of patients with vascular disease who are in need of expert consultation. In conjunction with this program, it is also expected that complementary educational and research programs will be developed or are already in place.

For the purpose of this award, vascular medicine is defined as the clinical discipline that has as its objectives: (1) clinical characterization, (2) pathogenesis, (3) diagnosis, (4) treatment, and (5) prevention of systemic and/or pulmonary vascular disease. To be responsive to this RFA, an application must provide for a program in systemic or pulmonary vascular disease or a combined program in both. A systemic vascular program should include cerebral, coronary, aortic, renal, peripheral and lymphatic circulations and address such disorders as atherosclerosis, lipid metabolic disorders, hypertension, lymphedema, thrombosis, vasculitis and vasospastic disorders. A pulmonary vascular disease program should include primary and secondary pulmonary hypertension, pulmonary vasculitis and pulmonary thromboembolism.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by November 30, 1994, a letter of intent, countersigned by the applicant's Department Chairman, Dean of the School of Medicine or Osteopathy, and Director of the Hospital(s). It should include a descriptive title of the proposed research, the name address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it assists the NHLBI staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

C. James Scheirer, Ph.D.
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 557
Bethesda, MD 20892

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research or may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Room 449, Bethesda, Maryland 20892, telephone 301 594-7248. Applications must be received by January 10, 1995.

REVIEW CONSIDERATIONS

Applications will be judged on the basis of the scientific and technical merit of the proposed research, the qualifications and research experience of the investigators, the collaborative interaction among clinical, educational and research components, the adequacy of the environment, and the appropriateness of the budget. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any questions from potential applicants are welcome. Direct requests for the RFA and Special Instructions, and inquiries regarding programmatic issues to:

Carol E. Vreim, Ph.D.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 6A16
Bethesda, MD 20892
Telephone: (301) 594-7430

Direct inquiries regarding fiscal matters to:

Mrs. Marie A. Willett
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A12
Bethesda, MD 20892
Telephone: (301) 594-7434

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.837, 93.838, and 93.839. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

NIH LOAN REPAYMENT PROGRAM FOR AIDS RESEARCH

NIH GUIDE, Volume 23, Number 24, June 24, 1994

PA NUMBER: PA-94-075

P.T. 34; K.W. 1014006, 0715008

National Institutes of Health

Application Receipt Dates: October 4, 1994; January 17; and June 1, 1995

PURPOSE

This notice updates a January 7, 1994 (Vol. 23, No. 1) issuance on this subject. Registered nurses (R.N.s) are now eligible to apply to this program. This publication is also being issued to announce the program's availability and application deadlines for fiscal year 1995.

The Health Omnibus Programs Extension Act of 1993 (Public Law 100-607), which was enacted on November 4, 1988, directed the National Institutes of Health (NIH) to establish a program of educational loan repayment to attract additional investigators into Acquired Immunodeficiency Syndrome (AIDS) research. The NIH Revitalization Act of 1993 (Public Law 103-43), enacted June 10, 1993, modifies and expands this established program. The NIH Loan Repayment Program for AIDS Research (LRP), in order to increase the number of investigators conducting AIDS research at the NIH, invites interested health professionals to seek NIH employment in AIDS research positions and apply for LRP participation.

Since LRP participation is limited to NIH employees, interested individuals should be actively seeking NIH employment opportunities that conform to the eligibility criteria stated in this announcement. Applicants must receive a written employment commitment and endorsement of the employing Institute, Center, or Division (ICD) of the NIH in order to be considered for the LRP.

As of June 10, 1993, individuals employed by the NIH during the period November 4, 1987, through November 3, 1988, are ELIGIBLE to apply and participate in the LRP subject to the other criteria and procedures described herein.

The LRP may pay a maximum of \$20,000 a year directly to a participant's lenders for qualifying educational debt during an initial, minimum two-year service period. The actual loan repayment is based, in part, on the availability of funding as well as the proportion of the participant's qualifying educational debt relative to their NIH basic pay or stipend. Qualifying educational debt amounts in excess of 50 percent of the debt threshold (see ELIGIBILITY REQUIREMENTS below) will be considered for repayment.

Since such repayments to lenders are considered income for the participant and increases his/her Federal tax liability, the LRP also makes payments, equal to 39 percent of the total loan repayments, directly towards the participant's Internal Revenue Service (IRS) account. The LRP may make additional tax reimbursements to those participants who show an increase in State and/or local tax liability. Benefits are paid in addition to a participant's annual NIH basic pay or stipend.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement describes the NIH Loan Repayment Program for AIDS Research, a program which is related to the priority area of HIV infection. Those interested may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

An applicant to the LRP is accepted for LRP participation when his/her qualified AIDS research assignment is approved by the AIDS Research Loan Repayment Committee (LRC) and his/her contract is executed. Specific LRP applicant and participant eligibility criteria include the following:

- (1) Applicants must be citizens or permanent residents of the United States;
- (2) Applicants must have a Ph.D., M.D., D.O., D.D.S., D.M.D., D.V.M., R.N., or equivalent degree;
- (3) Applicants must have qualified educational debt in excess of 20 percent of their annual NIH basic pay or stipend on the date of program eligibility (DEBT THRESHOLD), resulting from governmental or commercial loans obtained to support their undergraduate and/or graduate education;
- (4) Individuals with existing service obligations to Federal, State, or other entities will NOT be considered for the LRP unless deferrals are granted for the length of their LRP service obligation;

(5) Applicants must be appointed under a temporary or permanent employment mechanism which allows their employment with the NIH to last a minimum of two years;

(6) Individuals who are not NIH employees, such as Visiting Fellows, Intramural Research Training Award (IRTA) recipients, National Research Service Award (NRSA) recipients, Guest Researchers or Special Volunteers, NIH National Research Council (NRC) Biotechnology Research Associates Program participants, and Intergovernmental Personnel Act (IPA) participants, may NOT participate in the LRP; and

(9) Applicants will NOT be excluded from consideration under the LRP on the basis of age, race, culture, religion, gender, disability, or other non-merit factors.

In addition, in order to qualify for repayment, LRP applicants' debts are subject to the following limitations and restrictions:

The LRP will repay lenders for the principal, interest, and related expenses (such as the required insurance premiums on the unpaid balances of some loans) of qualified Government (Federal, State, and local) and commercial educational loans obtained by participants for the following: (1) undergraduate, graduate, and health professional school tuition expenses; (2) other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and (3) reasonable living expenses, including the cost of room and board, transportation and commuting costs, and other reasonable living expenses as determined by the LRP.

The following loans are NOT repayable under the LRP:

(1) loans not obtained from a Government entity or commercial lending institution, such as loans from friends, relatives, or other private individuals;

(2) loans for which contemporaneous documentation is not available;

(3) loans or portions of loans obtained for educational or living expenses which exceed the "reasonable" level as determined by the standard school budget for the year in which the loan was made, and are not determined by the LRP to be reasonable based on additional documentation provided by the applicant;

(4) loans, financial debts, or service obligations incurred under the following programs: Physicians Shortage Area Scholarship Program, National Research Service Award Program, Public Health and National Health Service Corps Scholarship Training Program, National Health Service Corps Scholarship Program, Armed Forces (Army, Navy, or Air Force) Health Professions Scholarship Program, Indian Health Service Scholarship Program, and similar programs which provide loans, scholarships, loan repayments, and other awards in exchange for a future service obligation;

(5) loans in default or not in a current payment status; and

(6) loan amounts which participants have paid or were due to have paid prior to the program eligibility date.

Repayments will only be made for loans in a current payment status. During lapses in loan repayments, due either to program administrative complications or a break in service, participants are wholly responsible for making payments or any other arrangements which maintain loans in a current payment status. Penalties assessed to participants as a result of LRP administrative failures to maintain current payment status may be considered for reimbursement.

RESEARCH OBJECTIVES

The LRP is designed to attract additional investigators into AIDS research. The LRP intends to fund individuals conducting AIDS research as described in the following paragraphs which contain the "Activities Constituting AIDS Research" criteria as adopted by the LRC, November 19, 1993:

"The following parameters define whether a proposed research assignment meets the criteria for coverage under the NIH Loan Repayment Program for AIDS Research - that is, whether the incumbent will be "primarily" engaged in AIDS research. "Primarily" engaged in AIDS research is defined as AIDS research activities that constitute at least 80 percent of a researcher's time. Clinical Associates, whose intent is to primarily engage in AIDS research, must engage in qualified AIDS research for at least three months in the first year of their program, with a total of fifteen months of qualified AIDS research during their two-year contract. AIDS researchers include registered nurses who are principal or associate investigators in AIDS research studies.

"AIDS research includes studies of the human immunodeficiency virus (HIV), the pathophysiology of HIV infection, the development of models of HIV infection and its sequelae, cofactors predisposing to HIV infection and AIDS, or its sequelae, and the development of vaccines and therapeutics. More specifically, the following research activities are included: (1) studies of HIV and related retroviruses; (2) studies of the mechanism(s) by which HIV and related retroviruses establish infection and infect host cells; (3) studies of the mechanism(s) by which HIV and related retroviruses cause disease, including studies of the immune deficiency induced by HIV and related retroviruses; (4) studies of the pathophysiology of host response to HIV infection; (5) studies of in vivo or in vitro models of human HIV infection and its sequelae; (6) epidemiologic studies of HIV and related retrovirus infection; (7) clinical trials involving prophylaxis or therapy for HIV infection or its sequelae; (8) preclinical studies aimed at the development of therapy for or prevention of HIV infection and the immunodeficiency caused by HIV infection and its sequelae; (9) cofactors predisposing to acquiring HIV infection and/or the progression of HIV-related disease; (10) basic studies and clinical trials involving vaccines, or other immunological or chemotherapeutic interventions for the prevention of HIV infection and its sequelae; (11) studies into the transmission of HIV involving high risk behaviors and research concerning the interruption of transmission by behavioral change and pharmacologic intervention; and (12) basic studies of the societal impact of and response to the HIV/AIDS epidemic, including subgroups within the population.

"AIDS researchers include scientists who are intellectually engaged in the process of providing scientific direction and guidance in programs of original AIDS research, specifically epidemiologists, statisticians, and others who are involved in the design and conduct of research studies. The duties of such scientists may include the generation and design of studies and the collation and analysis of data; and/or the preparation and publication, as author or co-author,

of studies in peer-reviewed journals.

"AIDS researchers also include physicians and registered nurses who are providing care for HIV-infected individuals who are subjects of HIV-related research."

APPLICATION PROCEDURES

An initiating official, who may be a laboratory or branch chief, must recommend an individual for application to the LRP, and the ICD Scientific Program Director and ICD Director must concur. Since LRP participation is contingent, in part, upon employment with the NIH, candidates may not be recommended for loan repayment by an ICD until a firm employment commitment has been made by the recommending ICD's Personnel Department.

ICD Loan Repayment Program Coordinators forward recommended applications to the Director, LRP, who submits eligible applications for consideration and approval/disapproval by the LRC. Recommended candidates may forward financial information directly to the Director, LRP.

At the conclusion of the initial contract, participants may reapply and be considered for subsequent, one-year continuation contracts. Continuation contracts are based upon the same review criteria as the initial contract, in addition to a description of AIDS research accomplishments made during the initial contract. These continuation contracts are approved on a year-to-year basis and contingent upon the appropriation and availability of funds.

REVIEW CONSIDERATIONS

The LRC reviews the scientific research portions of eligible LRP applications. The LRC, which is composed of intramural and extramural scientific staff, reviews, ranks, and approves or disapproves applications. LRC approval, in part, is based on the appropriateness of the research assignment to the LRP's AIDS research criteria (see above) and the scientific merit of the research. In addition, the credentials provided in the application are reviewed and ranked to assess the applicant's potential to conduct qualified AIDS research.

LRP program staff review and verify the financial portions of eligible applications and determine projected funding levels. Actual funding is dependent upon LRC approval and the terms of the LRP service contract.

AWARD CRITERIA

The award of funds for approved applications is contingent, in part, upon the availability of appropriated or allocated funds. Funds will not be awarded to disapproved applications. In return for the repayment of their educational loans, participants must agree (1) to be "primarily" engaged in qualified AIDS research, which is described above in the "Activities Constituting AIDS Research" criteria, as NIH employees for a minimum period of two years; (2) make payments to lenders on their own behalf for periods of Leave Without Pay (LWOP); (3) pay monetary damages as required in cases where the initial contract is breached; and (4) all other provisions agreed upon in their contracts. Substantial monetary penalties will be imposed for breach of contract.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Information regarding the LRP may be obtained from:

Mr. Sean E. Spann
Office of AIDS Research
National Institutes of Health
7550 Wisconsin Avenue, Room 102
Bethesda, MD 20892-9905
Telephone: (800) 528-7689

AUTHORITY AND REGULATIONS

The LRP is described in the Catalog of Federal Domestic Assistance under number 93.936. Awards are made under authorization of section 487A of the PHS Act (42 U.S.C. 288-1), as amended by section 634 of the Health Omnibus Programs Extension of 1988 (P. L. 100-607) and section 1611 of the NIH Revitalization Act of 1993 (P.L. 103-43). This program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs, and was granted clearance from the Office of Management and Budget (OMB) (0925-0361), under the requirements of the Paperwork Reduction Act of 1980, on June 15, 1990.

HEALTH SERVICES RESEARCH ON CLINICAL PREVENTIVE SERVICES

NIH GUIDE, Volume 23, Number 24, June 24, 1994

PA NUMBER: PA-94-076

P.T. 34; K.W. 0730050, 0404003, 0745027, 0715148

Agency for Health Care Policy and Research
National Institute on Alcohol Abuse and Alcoholism
National Institute on Dental Research

PURPOSE

The Agency for Health Care Policy and Research (AHCPR), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), and the National Institute of Dental Research (NIDR) invite health services research applications that will examine methods to improve the cost effectiveness and/or quality of clinical preventive services, or that will improve access to clinical preventive services.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement (PA), Health Services Research on Clinical Preventive Services, is related to the priority areas of clinical preventive services as well as related objectives from other priority areas. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-004374-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, including universities, clinics, units of State or local governments, firms, and foundations. The AHCPR can support only non-profit organizations. Applications from minority and women investigators are encouraged.

MECHANISM OF SUPPORT

This PA uses the research project grant (R01) mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant.

RESEARCH OBJECTIVES

Background

The AHCPR's purpose is to enhance the quality, appropriateness, and effectiveness of health care services through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice and in the organization, financing and delivery of health care services. This PA encourages research that furthers this purpose by helping translate disease-prevention knowledge into improved clinical preventive services. Preventive services are interventions intended to prevent disease or disability, or prevent specific sequelae from diseases. When initiated or delivered to individuals in a personal health care setting, these services are considered clinical preventive services. Examples are counseling for disease risk factors including advice to reduce health risks, screening for early detection of disease, chemoprophylaxis for individuals exposed to infections, and immunizations. The NIAAA and NIDR join AHCPR in interest in these areas when the study outcomes are related to alcohol use or oral health, respectively.

Most national health care reform proposals include preventive services as a necessary component of the health care system. Effective prevention programs have the potential to reduce diseases and associated use of medical services; this, in turn, may contribute to slowing the rate of increase in health care costs. The cost-effectiveness of specific methods and procedures for providing individual clinical preventive services must be determined by science-based research, and ways to improve cost-effectiveness must be sought. At the same time, there must be assurance that these services are of high quality and are readily accessible.

Research Goals

For this PA, "efficacy" refers to the probability of benefit under ideal conditions, while "effectiveness" refers to benefit that can be expected in typical situations. Factors that can change the probability of benefit of interventions, and thus also their effectiveness, include provider behaviors, skills, and techniques; and patient adherence/compliance and other characteristics. For preventive service programs, management and institutional characteristics may also affect benefit by increasing the proportion of targeted people receiving the intervention.

Recommendations for clinical preventive services are presented in the U.S. Preventive Services Task Force's Guide to Clinical Preventive Services. While efficacy of these clinical preventive services is generally accepted, the community benefit of many prevention programs has been disappointing. Research under this PA should lead to improved effectiveness of clinical preventive services in the community.

This PA seeks health services research on efficacy-proven clinical preventive services, not research on preventive services for which efficacy has not yet been established. Research is sought in the following three areas. These areas are interrelated, and applications may address one, two, or all three areas.

1. Cost-effectiveness

Cost constraints and movement towards competitive contracting for clinical services will increase the need for reliable

and acceptable cost-effectiveness data. Coverage for services, bundled services, and exclusions of services may be determined on the basis of cost-effectiveness and outcomes analyses. Cost-effectiveness studies examine the cost of alternatives to achieve a desired goal. Costs include direct medical costs, indirect costs, and psychological costs. Effectiveness relates to patient outcomes, and may include outcomes other than morbidity or mortality, such as functional status and quality of life. Examples of research topics include:

- o Cost-effectiveness of specific preventive services;
- o Comparison of practice standards, protocols, recommendations, and methods for the delivery of preventive services currently suggested by various organizations;
- o Effects of different practice management patterns on cost-effectiveness of clinical preventive services:
- o Cost-effectiveness of different approaches to health maintenance intended to preserve health and improve an individual's functional capacity, such as counseling and health education services, including approaches using certified non-physician providers;
- o Cost-effectiveness of clinical strategies for prevention of disease and disabilities that would otherwise lead to long-term care;
- o Evaluation of "bundling" preventive services, including cost-effectiveness of various preventive service "packages;" and
- o Advantages/disadvantages of innovative approaches for the delivery of infant, child, and adolescent clinical preventive services, particularly to underserved/vulnerable populations.

Methods Development. In addition to dollar costs, preventive services should be evaluated in other dimensions as well. It is important to develop and apply methods for assessing outcomes of clinical preventive services including: incorporation of quality-of-life measures and patient preferences into standardized methods of comparison; risk adjustment methods that allow for accurate comparisons of outcomes of clinical preventive services; and development of outcomes measures that incorporate functional assessment.

This list is illustrative only and is not meant to be restrictive. Important elements of original investigations in this area include the structure and concept of the analysis, the comparisons used, the use of appropriate descriptive and evaluative ratios such as relative risk, and the bases for sensitivity analyses.

2. Quality

Quality issues include timeliness, appropriateness of technique or procedure, avoidance of harm from the service, and relevance of the technique/procedure to the recipient. Many organizations are working to refine and formalize reliable and accurate quality measures. Often ambulatory care quality assessments are based on analysis of administrative data or claims and some measure of patient satisfaction. The feedback of comparative information is used as a stimulus for quality improvement. Although the administrative data- or claims-based analyses of preventive services can be broad in scope, there are limitations to the depth of analysis. Provision of services may be reported on claims, but such data provide no indication of the service's quality. Assessment of service quality has been difficult. Research is needed to develop more meaningful and efficient methods for measuring and improving the quality of clinical preventive services. Examples of research include, but are not limited to, the following:

- o What are the best measures of the quality of clinical preventive services? What is the comparative validity of patient reports, chart review, facility report card, or claims data? How can quality-of-service measures be standardized for fair comparison?
- o What are the best methods to ensure that follow-up of abnormal screening test results is timely; for example, how can the follow-up process be improved for patients with abnormal Papanicolaou tests?

3. Access

Improved availability of health care services for all citizens is a fundamental principle of most health care reform proposals. While availability may improve under health care reform, access may not necessarily improve for all people. Many factors affect access. Reducing preventive service access barriers may require a comprehensive preventive health systems management approach. In this sense, a preventive health system can be viewed as the sum of available resources for preventive services, and the organization, prioritization, and implementation of those resources. Systems management research may help determine the appropriate infrastructure and personnel needs for delivering clinical preventive services.

If health care reform removes financial barriers for individuals not presently covered, there may be more demand for both acute care and preventive health services. Preventive services that must be provided by physicians may not receive as much attention by either patients or physicians as treatment services. Competing demand for treatment services from physician providers may cause provision of preventive services to decline. New strategies to use nonphysician providers for clinical preventive services may increase capacity, and preserve or increase access to preventive services. For example, the feasibility of nurses performing sigmoidoscopy, as part of a team in a controlled system, has recently been demonstrated.

Technologic support also may increase access to clinical preventive health services. Computer-assisted information management may be useful. Health systems management research can define methods for integrating computer techniques into a comprehensive health plan for delivering preventive services.

Examples of research include, but are not limited to, the following:

- o Comparisons of technological support in different managed care systems and identification of characteristics that improve the delivery of preventive services;

- o Evaluation of the effect of new management systems/approaches on workforce needs; Implications, quality determinants, and feasibility of nursing and allied health professionals providing clinical preventive services in a logical, documented, and coordinated fashion;

- o Effectiveness of computer-based information systems in improving clinical preventive services access, and enhancement of such systems;

- o Advantages of different strategies to promote the use of available clinical preventive health services; and

- o Comparison of methods to increase the delivery of recommended clinical preventive services for those who come in for other health care and fail to get preventive services (missed opportunities), and for those who do not come in for health care (outreach).

Research Interests of NIAAA

Under the general framework of this PA, NIAAA has special interest in research related to alcohol use. Advice about alcohol use and brief interventions to reduce problem drinking have consistently been shown to be effective in reducing alcohol consumption and associated harmful consequences (Bein, Miller, Tonigan, Addictions 88:315-336, 1993). These interventions have been implemented in a variety of health care settings and the cost-effectiveness of these procedures needs to be directly evaluated. Prevention of alcohol misuse may also serve as a co-factor in use of other medical services. Of particular interest is the primary care setting, in which cost-effectiveness, quality of care, and accessibility of preventive medical services may be affected by type of intervention.

Examples of research may include, but are not limited to:

- o Modeling of current patterns of preventive services that address alcohol use. This includes attention to characteristics of different health care settings and special populations in order to identify optimal interventions and alcohol use or abuse on service usage. Settings could include office-based practices, emergency rooms, health maintenance organizations, or public health clinics. Special at-risk groups of interest could include adolescents, women of childbearing age, minority individuals or inner-city or rural populations.

- o Cost-effectiveness of these interventions in improving other health-care utilization patterns.

Related to the implementation of cost-effective preventive interventions is the study of methods to change attitudes of service providers to improve their acceptance of preventive alcohol interventions.

Research Interest of NIDR

Under the general framework of this PA, NIDR invites applications for research in which the dependent variable of interest is a component of oral health.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies. All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which were published in the Federal Register of March 20 1994 (FR 59 14508-14513), and printed in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the NIAAA or NIDR program contact listed under INQUIRIES. The NIAAA or NIDR program contact may also provide additional relevant information concerning the policy.

AHCPR supports this NIH policy, which supersedes and strengthens NIH's previous policies that the AHCPR had adopted. The AHCPR plans to publish guidelines on women and minorities specific to the AHCPR. In the interim, the AHCPR will follow the NIH guidelines, as applicable. The AHCPR program contact listed under INQUIRIES may also provide additional relevant information concerning AHCPR's policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91), and will be accepted at the standard application deadlines as indicated in the application kit. State and local government agencies may use form PHS 5161 and follow those requirements for copy submission. Application kits are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301-594-7248; and for AHCPR applications from Global Exchange Inc., 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814-3015, telephone 301-656-3100 (FAX 301-652-5264). The title and number of the PA must be typed in Section 2a on the face page of the application.

The completed, signed, original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness and responsiveness. Incomplete applications will be returned to applicants without further consideration. Review criteria for are:

- o scientific and technical significance of proposed research;
- o appropriateness and adequacy of the research approach and methodology proposed to carry out the research;
- o qualifications and research experience of the Principal Investigator and staff, particularly, but not exclusively, in the area of the proposed research;
- o availability of data or a well designed plan for gathering data necessary to perform the research;
- o appropriateness of the proposed budget and duration in relation to the proposed research.

Applications will be reviewed for scientific and technical merit in accordance with the criteria stated above by an appropriate peer review group. Applications recommended for funding consideration by the peer review group will be reviewed by an appropriate National Advisory Council; review by Council may be based on policy considerations as well as scientific merit.

There is interest in prevention-related research among other components of the National Institutes of Health. Applications may be referred to appropriate Institutes for consideration of funding or co-funding.

AWARD CRITERIA

Applications will compete for available funds with all other applications. The following will be considered in making funding decisions: quality of the proposed project as determined by peer review, availability of funds, and program balance. The earliest anticipated date of award is 10 months from the date of submission.

INQUIRIES

Those considering applying in response to this PA are strongly encouraged to discuss the project with program administrators in advance of formal submission. The AHCPR, NIAAA, and NIDR welcome the opportunity to clarify any issues or questions from potential applicants.

Direct inquiries regarding programmatic issues, including information on the policy of inclusion of women and minorities in study populations, to:

James K. Cooper, M.D.
Center for General Health Services Extramural Research
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 502
Rockville, MD 20852
Telephone: (301) 594-1354, ext. 141

Kendall J. Bryant, Ph.D.
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
6000 Executive Boulevard, Suite 505
Rockville, MD 20892-7003
Telephone: (301) 443-8820

Patricia S. Bryant, Ph.D.
Behavior, Pain, Oral Function and Epidemiology Program
National Institute of Dental Research
Westwood Building, Room 509
Bethesda, MD 20892
Telephone: (301) 496-7784

Direct inquiries regarding fiscal matters to:

Ralph Sloat
Grants Management Officer
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 601
Rockville, MD 20852
Telephone: (301) 594-1447

Edward B. Ellis
Grants Management Specialist
National Institute on Alcohol Abuse and Alcoholism
6000 Executive Boulevard, Suite 504
Rockville, MD 20892-7003
Telephone: (301) 443-4706

Teresa Ringler
Chief, Grants Management Office
National Institute of Dental Research
Westwood Building, Room 510
Bethesda, MD 20892
Telephone: (301) 594-7629

AUTHORITY AND REGULATIONS

These programs are described in the Catalog of Federal Domestic Assistance Nos. 93.226, 93.273, and 93.121. Awards are made under authorization of Titles IX and IV, and Section 301 of the Public Health Service Act. Awards are administered under the PHS Grants Policy Statement; and Federal Regulations 42 CFR Part 67 Subpart A, 42 CFR Part 52, 45 CFR Part 46, and 45 CFR Part 74 (45 CFR Part 92 for State and local governments). These programs are not subject to the intergovernmental review requirements of Executive Order 12372.

NEUROBIOLOGY OF ETHANOL-RELATED BEHAVIORS

NIH GUIDE, Volume 23, Number 24, June 24, 1994

PA NUMBER: PA-94-077

P.T. 34; K.W. 0404003, 0710085, 0404001, 0705048

National Institute on Alcohol Abuse and Alcoholism

PURPOSE

Understanding how ethanol consumption can alter behavior is an important goal of the National Institute on Alcohol Abuse and Alcoholism (NIAAA). Consequently, NIAAA is seeking research grant applications using state-of-the-art neuroscience and behavioral techniques to elucidate the cellular and molecular mechanisms underlying the acute and chronic actions of ethanol on the brain that mediate ethanol-induced behaviors. Animal and human studies are needed in which ethanol-induced behaviors, including ethanol-seeking behavior, motor incoordination, cognitive deficits, and aggression are coupled to changes in neurotransmitters and neuromodulators in the brain. Especially encouraged are applications that directly address specific mechanisms underlying medical and behavioral problems associated with excessive alcohol use, with a goal of developing prototypic therapeutic approaches.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Neurobiology of Ethanol-Related Behaviors, is related to the priority areas of alcohol abuse reduction and alcoholism treatment. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY

Applications may be submitted by domestic and foreign, public and private, non-profit and for-profit organizations, such as universities, colleges, hospitals, research institutes and organizations, units of State and local governments, and eligible agencies of the Federal government. Women and minority investigators are encouraged to apply. Only domestic institutions are eligible for First Independent Research Support and Transition (FIRST) Awards (R29). U.S. citizenship, however, is not required.

MECHANISM OF SUPPORT

Research support may be obtained through applications for regular research project grants (R01), FIRST awards (R29), exploratory/developmental grants (R21), and small grants (R03). Applicants for R01s may request support for up to five years. Small grants and exploratory/developmental grants are limited to two years for up to \$50,000 per year and \$70,000 per year, respectively, for direct costs. FIRST Award applications must be for five years. Total direct costs for the five-year period may not exceed \$350,000, or \$100,000 in any one budget period. FIRST awards, exploratory/developmental Grants, and small grants cannot be renewed, but grantees may apply for R01 support to continue research on the same topics.

Potential applicants for FIRST awards, Exploratory/Developmental Grants, and Small Grants may obtain copies of the specific announcements for these programs from the National Clearinghouse for Alcohol and Drug Information, P.O. Box 2345, Rockville, MD 20847-2345, telephone 301-468-2600 or 1-800-729-6686. Although program project grants (P01) will be considered for funding, due to budget constraints and NIAAA requirements for program balance, applications for P01s in the program areas of NIAAA are not generally encouraged. Applications for program projects should not be submitted without prior clearance by NIAAA program staff.

While NIAAA desires to stimulate research in this area, the amount of funding available will depend on appropriated funds, quality of research grant applications, and program priorities at the time of the award. In FY 1993, 29 new and competing renewal grants related to this program area were funded by NIAAA for approximately \$4.3 million in total costs.

RESEARCH OBJECTIVES

Abuse of alcoholic beverages is responsible for numerous medical and social problems, including alcoholism per se and brain-related toxicity. As noted in the Eighth Special Report to the U.S. Congress on Alcohol and Health, ethanol related mortality accounts for more than five percent of all deaths in the United States. This rate of mortality ranks behind only cardiovascular and cancer mortality.

In addition to ethanol addiction, important adverse behavioral consequences resulting from ethanol consumption are vehicular and occupational accidents and violence and aggression. Vehicular accidents result largely from cognitive and motor impairments that reduce performance and efficiency in such activities as driving a car or operating machinery. Violence and aggression after ethanol consumption are often expressed as homicide, suicide, rape, spousal battering, and child abuse. Depression and low self-esteem in ethanol abusers may contribute to antisocial behavior and suicide. Inappropriate sexual responses are often related to ethanol intake and may be expressed as sex crimes, including incest, date rape, and sexual abuse of children and the elderly.

Since the presence of ethanol in the brain and chronic exposure can alter biological mechanisms mediating behavior, the NIAAA requests applications that address those mechanisms underlying undesirable ethanol-induced behaviors.

Over the past 20 years, numerous reports have provided substantial evidence suggesting that acute and chronic ethanol administration alters various neurotransmitters and neuromodulators in the brain, leading to alterations in behavior. For example, dopamine and serotonin as well as opiates, aminobutyric acid (GABA), and possibly other neurotransmitters and hormones have been implicated in the reinforcing effect of ethanol. GABA and N-methyl-D-aspartate receptors have also been associated with the intoxicating properties of acute ethanol exposure and ethanol withdrawal. Interfering with these neurotransmitter-mediated events shows promise as a potential therapeutic strategy for treating the various behavioral complications of alcohol abuse and alcoholism.

Further research, taking into account genetic attributes, ethanol effects, and environmental factors, can help to ascertain whether or not ethanol-induced alterations in neurotransmitters and neuromodulators specifically cause changes in behaviors relevant to excessive ingestion of ethanol and/or to specific medical or social problems associated with alcohol abuse. Such studies will help identify potential targets for later therapeutic strategies to help reduce these problems.

Examples of areas needing further research include, but are limited to:

- o Development and application of appropriate animal protocols of ethanol-induced behavior changes, coupling in vivo measures of neurotransmitter release or neuroimaging techniques to behavioral paradigms that address relevant medical and social situations related to alcohol abuse and alcoholism.

- o Careful correlative studies assessing changes in specific neurotransmitters and neuromodulators in specific areas of the brain with appropriate behavioral end points directly relevant to the medical and social problems outlined above. Most relevant are studies using oral ethanol administration that relate blood ethanol concentrations to the behaviors monitored.

- o Use of innovative techniques, such as microdialysis, voltammetry, or single electrode recordings, in specific brain regions in freely behaving animals performing behavioral tasks relevant to the problems discussed above.

- o Use of genetically defined animals to further clarify the relationships between ethanol-related behavior and genetic differences in neurotransmitter systems.

- o Development of new techniques or innovative use of existing techniques for humans, such as PET and SPECT imaging that will allow simultaneous monitoring of neurotransmitter changes of individuals performing behavioral tasks relevant to the problems discussed above during ethanol intake.

- o Specific pharmacological manipulations of various transmitter systems to determine the extent to which ethanol-induced changes in relevant behaviors can be altered and to determine whether such alterations might have potential clinical relevance in ameliorating abnormal behaviors induced by ethanol consumption.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies. All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the program staff or contact person listed below. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (revised 9/91) and will be accepted at the standard application deadlines as indicated in the application kit.

Application kits are available from most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, Westwood Building, Room 449, National Institutes of Health, Bethesda, MD 20892, telephone 301-594-7248. The number and title of this program announcement must be typed in item number 2a on the face page of the application.

FIRST applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications received under this program announcement will be assigned to an appropriate Initial Review Group (IRG) in accordance with established PHS Referral Guidelines. The IRG, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit in accordance with standard NIH review procedures. Notification of the review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by an appropriate National Advisory Council, whose review may be based on policy considerations as well as scientific merit. Only applications recommended by the Council may be considered for funding. Small Grants (R03) do not receive a second level review.

Review Criteria

Criteria for scientific/technical merit review of applications for regular research grants (R01) are:

1. The overall scientific and technical merit and significance of the proposed research.
2. The appropriateness and adequacy of the experimental design, including the adequacy of the methodology proposed for collection and analysis of data.
3. The adequacy of the qualifications and relevant research experience of the principal investigator and key research personnel.
4. The adequacy of facilities and general environments necessary for the conduct of the proposed research, other resources, and any collaborative arrangements necessary for the research.
5. The appropriateness of budget estimates for the proposed research activities.
6. Where applicable, the adequacy of procedures to protect human and animal subjects and the environment.
7. Conformance of the application to the NIH policy on inclusion of women and minorities in study populations.

The review criteria for Small Grants (R03), Exploratory/ Developmental Grants (R21), and FIRST Awards (R29) are contained in their program announcements.

AWARD CRITERIA

Applications recommended by a National Advisory Council will be considered for funding on the basis of overall scientific and technical merit of the research as determined by peer review, program needs and balance, and availability of funds.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Walter A. Hunt, Ph.D.
Division of Basic Research
National Institute on Alcohol Abuse and Alcoholism
Willco Building, Suite 402
6000 Executive Boulevard
Rockville, MD 20892-7003
Telephone: (301) 443-4225
FAX: (301) 594-0673
Internet: WHunt@WILLCO.NIAAA.NIH.GOV

Direct inquiries regarding fiscal matters to:

Joseph Weeda
Office of Planning and Resource Management
National Institute on Alcohol Abuse and Alcoholism
Willco Building, Suite 504
6000 Executive Boulevard
Rockville, MD 20892-7003
Telephone: (301) 443-4703
FAX: (301) 443-3891

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.273. Awards are made under the authorization of the Public Health Service Act, Sections 301 and 464H, and administered under the PHS policies and Federal Regulations at Title 42 CFR Part 52, "Grants for Research Projects;" Title 45 CFR Parts 74 and 92, "Administration of Grants;" and 45 CFR Part 46, "Protections of Human Subjects." This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NATIONAL RESEARCH SERVICE AWARD INSTITUTIONAL RESEARCH TRAINING GRANTS

NIH GUIDE, Volume 23, Number 24, June 24, 1994

P.T. 44; K.W. 0720005, 0710030

National Institutes of Health

The following change is made to the NRSA Institutional Research Training Grants, which was published in the NIH Guide for Grants and Contracts, Vol. 23, No. 21, June 3, 1994:

REVIEW SCHEDULE

Application Receipt Date:	Jan 10	May 10	Sep 10
Initial Review Meeting:	Jun	Oct/Nov	Feb/Mar
Council/Board Meeting:	Sep/Oct	Jan/Feb	May/Jun
Earliest Start Date:	Dec 1	Apr 1	Jul 1

Many institutes review applications once per year. A table listing these institutes and the appropriate receipt dates is provided below.

Institute or Center	Application Receipt Date
NICHD	Jan 10
NEI	Jan 10
NIAAA	May 10
NIDCD	May 10
NIEHS	May 10
NIMH	May 10
NINDS	May 10
NINR	May 10
NIDR	Sep 10

****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

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Bethesda, MD 20816

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National Institutes of Health

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AND HUMAN SERVICES

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 25
July 1, 1994

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

THE PUBLIC HEALTH SERVICE (PHS) STRONGLY ENCOURAGES ALL GRANT RECIPIENTS TO PROVIDE A SMOKE-FREE WORKPLACE AND PROMOTE THE NON-USE OF ALL TOBACCO PRODUCTS. THIS IS CONSISTENT WITH THE PHS MISSION TO PROTECT AND ADVANCE THE PHYSICAL AND MENTAL HEALTH OF THE AMERICAN PEOPLE.

THE NIH GUIDE FOR GRANTS AND CONTRACTS WILL NOT BE PUBLISHED ON JULY 8, 1994. THE NEXT ISSUE WILL BE JULY 15, 1994.

NOTICE OF PROPOSED RULEMAKING - OBJECTIVITY IN RESEARCH

NIH GUIDE, Volume 23, Number 25, July 1, 1994

P.T. 34; K.W. 1014006

Public Health Service

The following is a reprint of the Notice of Proposed Rulemaking, which was published in the Federal Register of June 28, 1994.

SUMMARY: The Public Health Service (PHS) proposes to issue rules requiring Institutions that apply for research funding from the PHS to assume responsibility for ensuring that the financial interests of the employees of the Institution do not compromise the objectivity with which such research is designed, conducted, or reported.

Under the proposed rules, investigators are required to disclose to an official(s) designated by the Institution a listing of Significant Financial Interests. The institutional official(s) will review these disclosures in accordance with an administrative process to be established by each institution. Following this review, the institutional official(s) will determine the acceptability of the reported financial interests and act to protect PHS-funded research from any bias that is reasonably expected to arise from those interests.

DATES: To ensure consideration, comments must be received at the address below on or before August 29, 1994.

ADDRESS: Please address comments to: Dr. George J. Galasso, Associate Director for Extramural Affairs, National Institutes of Health, Shannon Building, Room 152, 9000 Rockville Pike, Bethesda, Maryland, 20892. The PHS encourages persons with disabilities to use auxiliary devices and services to submit comments.

FOR FURTHER INFORMATION CONTACT: Dr. George J. Galasso, Associate Director for Extramural Affairs, National Institutes of Health at the address above. The telephone number is (301)-496-5356 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION

Technology Transfer and Conflict of Interest.

Effective interaction between PHS-funded Institutions conducting research and industry is essential to ensure the rapid application of scientific discoveries to the health needs of the Nation and to maintain the international competitiveness of domestic industry. Nonetheless, prudent stewardship of public funds includes protecting Federally funded research from being compromised by the conflicting financial interests of any Investigator responsible for the design, conduct, or reporting of PHS-funded research.

Numerous statutes and programs demonstrate the Federal interest in the promotion of interactions among Government, academia and industry. For example, the Stevenson-Wydler Technology Innovation Act of 1980 (Public Law (P.L.) 96-480) encourages technology transfer, particularly through industrial-academic collaborations. The Patent and Trademark Act Amendments of 1980 (P.L. 96-517) allow universities and other funding recipients to apply for patents developed with Federal funding, and expressly promote collaboration between commercial concerns and nonprofit organizations. The Economic Recovery Tax Act of 1981 (P.L. 97-34) is aimed at fostering research and development by small companies and associated university partners. The Federal Technology Transfer Act of 1986 (P.L. 99-502), which amended P.L. 96-480, and Executive Order 12592 provide similar patent and licensing authority to Federal laboratories, and encourage them to participate in cooperative research and development agreements with the private sector and nonprofit organizations, including universities.

These legal authorities facilitate the movement of intellectual capital between the Federal Government, academic institutions, and the private sector. This kind of cross-fertilization is critical to the development of the U.S. biotechnology industry. However, these and other inducements for collaboration, as well as the rapid growth of the biotechnology industry, have created a climate in which the stewardship of public funding for biomedical and behavioral research is increasingly complex and challenging.

The value of the results of PHS-funded research to the health and the economy of the Nation must not be compromised by any financial interest that will, or may be reasonably expected to, bias the design, conduct or reporting of the research. The proposed regulations seek to maintain a reasonable balance between these competing interests, give applicants for PHS research funding responsibility and discretion to identify and manage financial interests that may bias the research, and minimize reporting and other burdens on the applicants.

Background

The proposed regulations are the result of a lengthy process of consideration. Throughout that process, the PHS has carefully considered and changed its approach in response to public comments.

On June 27 and 28, 1989, the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) sponsored an open meeting to discuss issues related to financial conflict of interest. At that meeting there was general agreement that an Institution that receives research funds from a PHS Awarding Component should develop policies to identify and manage any financial conflict of interest in the funded research.

On September 15, 1989, the NIH and ADAMHA published a Request for Comment on Proposed Guidelines for Policies on Conflict of Interest in the NIH Guide for Grants and Contracts (Volume 18, Number 32). Seven hundred fifty-one responses were received from individuals associated with medical schools, other academic and research institutions, biotechnology companies, local governments, and non-profit organizations; venture capitalists; attorneys; biomedical journal editors; Federal employees and contractors at Government facilities; and others. In general, those submitting comments were concerned that the proposed guidelines imposed undue burdens on funded institutions and would impede mutually beneficial

research collaboration between universities and industry. In response to these comments, the Secretary determined that regulations should be developed that would address those concerns.

A public meeting was held at NIH on November 30, 1990, to discuss further the regulation of financial conflict of interest by the PHS. The 18 written comments received at that time reflected views similar to those received earlier.

Many respondents to earlier proposals stated that the primary responsibility for setting guidelines and maintaining compliance should rest with each awardee Institution. The present proposed rule, like PHS policy in other areas involving protection of the public interest (such as the protection of human subjects in research and the investigation of alleged scientific misconduct), sets standards for performance and assigns the primary responsibility for procedural development and compliance to the Institution.

Many of those commenting on prior proposals agreed with the importance of disclosure, but thought that the requirement to disclose all financial interests, as set forth in the previously proposed guidelines, should be reduced in scope to prevent needless invasion of privacy and creation of paperwork burdens. The proposed regulations achieve this end by limiting the disclosures that must be made to "Significant Financial Interests," any interest of monetary value exceeding a defined threshold of value (\$5,000) or percentage of ownership (five percent or more) that would reasonably appear to be directly and significantly affected by the research funded by PHS or proposed for funding. PHS specifically requests public comment on whether the minimum threshold for disclosure is appropriate to ensure that PHS-funded research projects are not biased by conflicting financial interests of those responsible for the design, conduct, or reporting of the research.

There was a wide range of opinion among those commenting on previous proposals regarding which types of financial interest should be permissible. In these proposed rules a Significant Financial Interest (defined in § 50.603) of the type specified in § 50.605(a) must be managed as provided in § 50.605(b) and the existence and management, reduction, or elimination of that financial interest must be certified in the application. The PHS may at any time request submission of, or review on site, all records pertinent to the certification. This procedure gives Institutions broad discretion in determining how to manage Significant Financial Interests that reasonably appear to directly and significantly affect the design, conduct, or reporting of the research while providing for appropriate PHS oversight. PHS may undertake periodic reviews of the records in order to assess the reliability of institutional and investigator certifications, and to determine whether institutional safeguards do, in fact, protect the integrity of PHS-funded research. In undertaking any such review HHS will coordinate, to the extent feasible, with the National Science Foundation (NSF) to ensure that institutions are not unnecessarily subjected to multi-agency reviews.

Managing potential conflicts carefully; avoiding unnecessary burden and useless paperwork; and preserving appropriate incentives for productive research represent challenges individually and collectively. Even after we issue a final rule some unforeseen problems will certainly emerge. Therefore, approximately one year after the final rule is issued we plan to initiate an evaluation, to include a conference and other mechanisms to consult with investigators and institutions. Based on that evaluation, we would revise these rules if and as appropriate.

Basis and Purpose. A more detailed discussion of the proposed regulations and their basis and purpose follows.

I. Applicability.

a. Types of Research. The proposed regulations implement section 493A of the PHS Act, added by Public Law 103-43, which mandates the issuance of regulations defining, and setting standards for, the management of financial interests that will, or may be reasonably expected to, bias a clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment. In addition, the proposed regulations implement section 924 of the PHS Act, as amended by Public Law 102-410, which requires the Administrator of the Agency for Health Care Policy and Research (AHCPR) to issue regulations defining the financial interests that will, or may be reasonably expected to, create a bias in the health care services research projects funded by the AHCPR. The proposed regulations are not limited to the implementation of these statutory authorities, however. Pursuant to the Secretary's authority to issue regulations governing those who seek or receive PHS funding, they apply broadly to all research funded by the PHS, whether under the authority of the PHS Act or other statutes, except Phase I projects under the Small Business Innovation Research (SBIR) Program. Very limited amounts of funding are provided under Phase I of the SBIR Program to plan and determine the feasibility of the research project for further funding under Phase II. Because potentially biasing financial interests will be assessed at the time of the Phase II application, it would be burdensome and unproductive to require such a review for Phase I applications. With this exception, it is believed that financial interests can create a bias in all types of research, although the likelihood of such a bias may diminish if the outcome of the research would have little effect on the commercial potential of any product, device, or other property in which the Investigator may have a financial interest. However, this distinction can not be so clearly drawn that the need to protect the integrity of all PHS-funded research uniformly is alleviated.

b. Individual vs. Institutional Financial Interests. The proposed regulations provide for the disclosure and consideration of the financial interests of individuals involved in the design, conduct, and reporting of the research. Section 493A of the PHS Act, added by Public Law 103-43, refers to financial interests of entities (e.g., institutions), as well as individuals, in clinical research projects. We are considering the following alternatives with respect to the coverage of institutions that apply for clinical research funding under the PHS Act:

(1) Exempting Institutional Financial Interests that Would Not Bias the Project. Under the statute, adoption of this alternative would be based on a determination that the exempted institutional financial interests would not be reasonably expected to bias the design, conduct, or reporting of PHS-funded research. This conclusion might be based on a finding that the limited size of the interest would preclude any biasing effect, or a finding that the institutional financial interest would have only an indirect and unpredictable effect on the project, in the absence of a personal financial interest on the part of those responsible for the design, conduct or reporting of the research. There would, of course, have to be a reasonable factual basis for such findings.

(2) Requiring Institutional Applicants to Certify Whether They Have Significant Financial Interests. Adoption of this alternative would involve establishing a procedure for institutions similar to the procedure in the proposed regulation for individuals. This option would be based on the same rationale as the preceding option, i.e. that there is no need to regulate institutional financial interests that aren't reasonably expected to bias the conduct of the research. Significant Financial Interest might be defined for institutions as limited only to direct financial interests (such

as a patent application on, or a financial arrangement with a company regarding, the product of the research).

(3) Requiring Full Disclosure to the PHS of the Financial Interests of Institutions. This alternative would impose a reporting burden upon the institutions, but would ensure a complete PHS review of any potential conflict of interest prior to a funding decision.

(4) Other Alternatives. We will also consider combinations of these three alternatives and other alternatives that may be suggested in the public comments. We will choose an alternative based on the requirements of the statute, and, to the extent consistent with the statute, based upon our weighing of the burdens on the institutions, the potential that institutional financial interests will bias PHS-funded research, and the potential adverse effect of the alternative upon technology transfer.

c. Types of Interests. The proposed regulations require disclosure of "significant financial interests" of the Investigator that would reasonably appear to be directly and significantly affected by the research funded by PHS or proposed for funding or of the investigator in an entity whose financial interest would reasonably appear to be directly and significantly affected by the PHS research. The following are examples of the types of significant financial interests that would fall within the categories in § 50.605: ownership of stock, stock options, or any equity, debt, security, capital holding, salary or other remuneration, or financial consideration, or thing of value for services as an employee, consultant, officer, or board member in (1) any business enterprise, including the applicant for PHS funds (except SBIR applicants are not included), that owns or has applied for the patent, manufacturing or marketing rights to a drug, vaccine, device, procedure or any other product involved in or that will predictably result from the research described in the application or (2) a business enterprise that is known by the investigator to own or have applied for such rights in any product that can reasonably be expected to compete with the product or procedure that will predictably result from the research described in the application. We request comments on a range of disclosures that would on the one hand, include interests that may threaten objectivity; and, on the other exclude those interests that cannot reasonably be regulated or that are so obvious as not to warrant regulation. We also request comments on whether specific examples of biasing significant financial interests, such as those set forth above, should be included in the regulations.

In particular, we request comments on whether interests in a business enterprise that is known by the investigator to have an interest in a product that competes with the product involved in the application should fall within the categories of significant financial interests described in § 50.605. There may not be any reasonable way for an investigator either to identify all competing products or to determine what companies own them. For example, for most medical devices there may be dozens of competing products, many made by subsidiaries of "Fortune 500" conglomerates. How would an investigator determine just what products were "competing"? Should we be concerned if an investigator owns \$5,000 of stock in a company in which only a small fraction of revenues and profits derive from the competing product? We request comments on whether, and how best, to cover interests in competing products.

We also request comments on whether an employee's stock or other non-salary financial interests in the applicant institution should be covered. This is of particular relevance when the grant or contract is with a for-profit enterprise. Specifically, should we be concerned, and how could we expect the company to "manage" against conflict, when the company's employees obviously stand to benefit if the product is a commercial success? The proposed rule includes an exemption for an ownership interest in the institution if it is an Small Business Innovation Research (SBIR) applicant. Can we justify exempting SBIR awards and not all other awards to both large and small profit-making enterprises? Should we exempt from disclosure any equity or ownership interest in the applicant institution? Should we exempt disclosure of interests other than bonuses or other compensation tied to the outcome of the research?

II. Burdens Upon Applicants. The proposed regulation is intended to minimize reporting and other burdens upon applicants to the maximum extent feasible. Certain types or amounts of financial interests that cannot be reasonably expected to bias the research are excluded from the requirements for disclosure by investigators. Such interests are also excluded from the certification of whether these are Significant Financial Interests that must accompany each application. Even when there is a Significant Financial Interest of the type specified in the proposed rule, the institutions are given broad discretion in managing the conflict; details of the interest need not be reported to the PHS awarding component. It is the responsibility of that component to determine whether to review the institutional records relating to the disclosure and management of that interest.

The Department will also seek to reduce burdens upon applicants by being available to provide advice and assistance as applicants establish the policies and procedures required by this subpart. The PHS Awarding Components will be available to respond to general inquiries regarding compliance with this subpart.

Another way of reducing burdens upon applicants is to exempt certain types of applicants from the requirements or to impose different, less burdensome requirements on them. The proposed § 50.602 provides that the regulations do not apply to SBIR Phase I applications and that where the applicant for a research grant is an individual, determinations of the procedures to be followed to ensure the objectivity of the research will be made on a case-by-case basis. The National Science Foundation (NSF) exempts from its Investigator Financial Disclosure Policy that is being published in this issue of the Federal Register grantees employing fifty persons or less. Comment on whether HHS should adopt a similar exclusion is requested. Our experiences with conflict of interest situations indicate that investigators working for small entities may be just as subject to conflicts of interest as investigators working at large institutions. The interests of appropriate coverage and of reducing burdens might both be served by determining the procedures to be followed by small entities on a case-by-case basis as is proposed for individuals.

III. Uniform Federal Policy. We have been working closely with the National Science Foundation (NSF) to ensure that this Notice of Proposed Rulemaking and the policy published by NSF in this issue of the Federal Register will be consistent, and will impose the same obligations on funding recipients. In addition, HHS has been working with the Office of Science and Technology Policy, the Office Management and Budget, NSF, and other interested agencies to develop and propose a common Federal policy on investigator conflicts of interest. It is expected that this policy, when completed, will ensure consistent treatment of investigator conflicts issues by all Federal funding agencies.

However, the statutes described above have necessitated some inconsistencies between these proposed regulations and the policy being published by the NSF. Unlike the NSF policy, there is no provision permitting institutions to waive the management, reduction, or elimination of an actual or potential conflicting interest when such action would be either

ineffective or inequitable, and the potential negative impacts that might arise from the conflicting interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare. Because section 493A of the Public Health Service Act requires institutions conducting PHS-funded clinical research projects to manage or eliminate financial interests that would potentially bias the project, we do not believe HHS has the discretion to permit institutions to waive this requirement. Similarly, section 493A necessitates the requirements for institutional notification of the PHS Awarding Component in § 50.604(a)(7)(ii) and (8). In addition, the statute specifically requires the announcement, with each public presentation of the research, of a conflicting financial interest that was not managed, reduced, or eliminated, as set forth in § 50.606(d). This requirement is limited to PHS-funded clinical research projects, but the requirements of institutional notification to the PHS have not been so limited, because we believe that such notification serves a useful purpose for all PHS-funded research, and that disparate reporting requirements for different types of research would cause confusion and create burdens for the institutions.

The Department notes that "management of a financial interest that could potentially bias a project" may include recognition by the institution that a potential conflict exists, and monitoring progress of the research to insure that the financial interest does not bias the project. The Department specifically requests comment on whether this interpretation maximizes consistency between this NPRM and the NSF's final policy, in the light of the statutory distinctions discussed above. The Department seeks comment on whether this expansion of the statutory requirement is appropriate in the context of PHS-funded research and the need to minimize burden on institutions.

IV. Relationship to other laws. Many Institutions funded by the PHS Awarding Components are State Institutions whose employees are subject to State laws designed to prevent financial conflict of interest. The proposed rules would not supplant these requirements and are intended to be applied in addition to other applicable Federal and State restrictions related to potential financial conflicts of interest, including Federal statutes and regulations that prohibit trading in securities with knowledge of privileged or non-public information.

V. Enforcement. The proposed regulations provide for enforcement remedies both against researchers that fail to comply with institutional policies issued under the regulation and Institutions that fail to comply with the regulation. The proposed rules specifically state that the requirements constitute a condition of award and as such could be enforced through the suspension or termination of a grant or cooperative agreement. A Termination for Convenience or a Stop Work Order could be issued in accordance with the FAR if a contractor fails to enforce the Special Standards. Each contractor would be required to meet the specified responsibility requirements prior to award of a contract. PHS awarding components will work diligently with applicants to resolve compliance problems informally, to avoid the need for formal enforcement action.

E.O. 12866/Regulatory Flexibility Act Analysis. Executive Order 12866 requires us to prepare an analysis for any rule that meets one of the E.O. 12866 criteria for a significant regulatory action, that is, that may --

Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments, and communities;

Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

Materially alter the budgetary impact of grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

In addition, we prepare a regulatory flexibility analysis, in accordance with the Regulatory Flexibility Act, if the rule is expected to have a significant impact on a substantial number of small entities.

For reasons outlined below, we do not believe this rule is economically significant nor do we believe that it will have a significant impact on a substantial number of small entities. In addition, this rule is not inconsistent with the actions of any other agency. However, we recognize that there are potential inconsistencies depending on what other agencies may later propose. Several agencies are now considering issuing policies on what circumstances are likely to lead to bias in research that is funded or relied upon by the Federal Government.

Any rule in this area has the potential to inhibit socially beneficial research, and to hamper the technological progress so essential to the American economy and to the advance of science. We are further mindful of the importance of the requirements in Executive Order 12866 that any new regulatory system be based on a showing that there is a significant problem requiring regulation, that regulatory priorities be based on the degree and nature of risks, and that regulations be designed to be cost-effective. Moreover, the Regulatory Flexibility Act requires us to minimize adverse effects not only on small businesses and individual entrepreneurs, but also on almost all non-profit entities including universities.

In the hearings that preceded enactment of the requirement in the NIH Revitalization Act, known cases were described in which scientists have stood to make large sums of money contingent on the positive outcome of research on a particular product, where this fact was not known to those reviewing the research, and where bias did occur.

We have drafted this rule to address these instances of abuse, while minimizing unnecessary burden to researchers. We did not consider any option that would routinely require all researchers to list all of their significant assets (unrelated to the research project), that would encourage searches for hypothetical or speculative conflicts, that would require divestiture of ownership of a product undergoing research, or that would discourage in any way funding grants or contracts to scientists to develop products with significant profit potential. We have not inhibited research in any way, other than requiring that it be managed to assure that potential bias is minimized. Such management methods are common in the sciences and impose no undue burden.

We request comment on whether there are any provisions of the proposed rule that might inadvertently hamper socially desirable research. For example, we have proposed allowing institutions to require that researcher employees divest themselves of stock in companies owning products undergoing research. Conversely, if there are other types of situations in which a financial conflict of interest has a substantial risk of biasing research results, we will consider expanding

the scope of the rule. We ask that commenters provide evidence as to magnitude and frequency of any claimed adverse effects or loopholes.

We do not believe that the annual costs of implementing this rule will reach as much as \$1,000 an institution in staff time, or as much as \$1 million a year across all institutions. Most of the cost will arise from the several seconds or minutes spent certifying the absence of significant financial interests for individual awards. Spread across thousands of grantee and contractor institutions, these costs are infinitesimal. Therefore, we have determined that this rule would not create an "unfunded mandate" imposed on state-owned institutions and would not trigger the requirements of Executive Order 12875, on "Enhancing the Intergovernmental Partnership."

For these same reasons, we certify that this rule will not have a significant economic impact on a substantial number of small entities, and that a Regulatory Flexibility Analysis is not required.

2. Paperwork Reduction Act

The proposed rules contain information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. Appropriate instructions for making certifications to the PHS Awarding Components will be issued as an addendum to the instructions for applications for PHS research funding. It is contemplated that the certification will be provided by checking a box on the application. The title, description, and respondent description applicable to the information collection are shown below with an estimate of the annual reporting and record-keeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought

Description: The regulations would require each applicant/offeror Institution to establish procedures to avoid the inappropriate financial interest of an Investigator involved in the design, conduct or reporting of the research for which PHS funding is sought.

Description of Respondents: Public and private non-profit institutions, small businesses, and other for-profit organizations.

ESTIMATED ANNUAL REPORT AND RECORD KEEPING BURDEN

Applicable section of Regulation 42 CFR	Applicable section of Regulation 45 CFR 94	Total Number of Respondents	Hours per Response	Total Hours 42 CFR	Total Hours 45 CFR	Total Hours
<u>Reporting:</u>						
50.604(a)(8)	(d)(1)(viii)	20	10.0	160	40	200
50.604(b)	(d)(2)	100	10.0	850	150	1,000
50.606(a)	(f)(1)	20	10.0	160	40	200
SUB-TOTAL:						1,400
<u>Record keeping:</u>						
50.604(a)(5)	(d)(1)(v)	2,000	100.0	180,000	20,000	200,000
SUB-TOTAL:						200,000
<u>Disclosure:</u>						
50.604(a)(1)	(d)(1)(i)	2,000	10.0	18,000	2,000	20,000
50.604 (a)(3)	(d)(1)(iii)	50,000	1.0	45,000	5,000	50,000
SUB-TOTAL						70,000
TOTAL BURDEN						271,400

In accordance with the requirements of the Paperwork Reduction Act of 1980, the Department of Health and Human Services will submit the information collection requirements cited above to OMB for review and approval. Organizations and individuals desiring to submit comments on the information collection requirements and the estimated burden should direct such comments to the information address cited above and to: NIH/PHS Desk Officer, Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Room 3208, 725 17th St., N.W., Washington, DC 20503.

Catalogue of Federal Domestic Assistance

The proposed rules affect all research, research and development, and research and development support funded by the Public Health Service. Questions about the proposed rules should be directed to the Information Contact provided above.

List of Subjects

42 CFR Part 50, Subpart F - Grant programs--health; Conflict of interest; Medical research; Behavioral, biological, biochemical, psychological and psychiatric research

45 CFR Part 94 - Government procurement.

Dated: June 16, 1994

Philip R. Lee, M.D.
Assistant Secretary for Health

Donna E. Shalala
Secretary

Accordingly, it is proposed to amend 42 CFR part 50 by adding a new Subpart F, and to amend 45 CFR by adding a new Part 94, as set forth below:

1. Subpart F is added to 42 CFR Part 50 to read as follows:

Subpart F--Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought

- 50.601 Purpose.
- 50.602 Applicability.
- 50.603 Definitions.
- 50.604 Institutional responsibility regarding Significant Financial Interests of Investigators.
- 50.605 Management of Significant Financial interests.
- 50.606 Remedies.
- 50.607 Other HHS regulations that apply.

Authority: 42 U.S.C. 216, 289b-1, 299c-3.

§ 50.601 Purpose.

This subpart promotes objectivity in research by requiring that each Institution that applies for PHS grants or cooperative agreements for research ensure there is no reasonable expectation that the design, conduct, and reporting of the research to be funded pursuant to the application will be biased by any Significant Financial Interest of an Investigator responsible for the design, conduct, or reporting of the research.

§ 50.602 Applicability.

This subpart is applicable to each Institution that applies for PHS grants or cooperative agreements for research and, through the implementation of this subpart by each Institution, to each Investigator participating in research covered by this subpart; provided, that this subpart does not apply to SBIR Program Phase I applications. In those few cases where an individual, rather than an institution, is an applicant for PHS grants or cooperative agreements for research, PHS Awarding Components will make case-by-case determinations on the steps to be taken to ensure that the design, conduct, and reporting of the research will not be biased by any Significant Financial Interest of the individual.

§ 50.603 Definitions.

As used in this subpart:

"HHS" means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

"Institution" means any domestic or foreign, public or private, entity or organization (excluding a Federal agency).

"Investigator" means the principal investigator and any other person at the Institution who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For the purposes of the requirements of this subpart relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children.

"PHS" means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

"PHS Awarding Component" means the organizational unit of the PHS that funds the research that is subject to this subpart.

"Public Health Service Act" or "PHS Act" means the statute codified at 42 U.S.C. 201 et seq.

"Research" means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement whether authorized under the PHS Act or other statutory authority.

"Significant Financial Interest" means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

- (1) salary, royalties, or other remuneration from the institution; or any ownership interests in the institution, if the institution is an applicant under the SBIR Program;
- (2) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- (3) income from service on advisory committees or review panels for public or nonprofit entities; or
- (4) financial interests in business enterprises or entities if the value of such interests do not exceed \$5,000 per annum if salary, fees or other continuing payments or represent more than a five percent ownership interest for any one enterprise or entity when aggregated for the investigator and the investigator's spouse and dependent children.

"Small Business Innovation Research (SBIR) Program" means the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

§ 50.604 Institutional responsibility regarding Significant Financial Interests of Investigators.

(a) Each Institution must:

(1) Inform each Investigator of the Institution's policy for identifying and managing Significant Financial Interests, the Investigator's reporting responsibilities, and of this subpart.

(2) Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

(3) Ensure that Investigators have provided to the designated official(s) a listing of Significant Financial Interests that ensures disclosure of all Significant Financial Interests of the type described in § 50.605(a) prior to the time an application is submitted to PHS. All financial disclosures must be updated during the pendency of the award, either on an annual basis, or as new reportable Significant Financial Interests are obtained.

(4) Provide guidelines consistent with this subpart for the designated official(s) to identify Significant Financial Interests of the type described in § 50.605(a) and take such actions as necessary to ensure that any such financial interest will be managed, reduced, or eliminated.

(5) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Institution with respect to each Significant Financial Interest of the type described in § 50.605 for at least three years beyond the termination or completion of the award, or until resolution of any action by the HHS involving the records, whichever is longer.

(6) Establish procedures for resolving any alleged violation of the financial conflict of interest policy of the Institution and establish appropriate enforcement action for failure to comply.

(7) Certify, in each application for the funding to which this subpart applies, that:

(i) there is in effect at that Institution a written and enforced administrative process to identify and manage, reduce or eliminate Significant Financial Interests of the type described in § 50.605(a) with respect to all research projects for which funding is sought from the PHS,

(ii) the Institution either has, or has not found a Significant Financial Interest of the type described in § 50.606 and, where such interest is found, certify that actions will be taken prior to the award of funding to manage, reduce or eliminate that interest in accordance with this subpart; and that the Institution will notify the PHS Awarding Component of such action prior to issuance of the Notice of Grant Award.

(iii) the Institution agrees to make information available, upon request, to the HHS regarding all Significant Financial Interests identified by the Institution of the type described in § 50.605 and how those interests have been managed, reduced, or eliminated to protect the research from bias;

(iv) the Institution will otherwise comply with this subpart.

(8) (i) Notify the PHS Awarding Component of the identification and management, reduction or elimination of any Significant Financial Interest of the type described in § 50.605 that originates or becomes known to the institution after the grant or cooperative agreement has been awarded, within sixty days of its becoming aware of that interest.

(ii) The HHS may at any time request submission of, or review on site, all records pertinent to these certifications. To the extent permitted by law, all records of financial interests will be maintained confidentially.

(iii) An investigator may participate in a PHS-funded research project that is being simultaneously supported by an organization that has a commercial interest in the finding of the research project. However, the research support must be provided through the PHS awardee Institution. Any direct compensation or payment to the Investigator under that support is considered a financial interest under this subpart.

§ 50.605 Management of Significant Financial Interests.

(a)(1) Institutions applying for PHS funding for research shall ensure that the following types of Significant Financial Interests attributable to an Investigator are managed, reduced, or eliminated, in accordance with paragraph (b) of this section, prior to award of the grant:

(i) any Significant Financial Interest of the Investigator that would reasonably appear to be directly and significantly affected by the research funded by PHS, or proposed for funding; and

(ii) any Significant Financial Interest of the Investigator in an entity whose financial interest would reasonably appear to be directly and significantly affected by the research funded by PHS, or proposed for funding.

(2) In addition to the types of Significant Financial Interests described in this paragraph that must be managed, an Institution may require the management of other financial interests as the Institution deems appropriate.

(b) The designated official(s) must review all financial disclosures, determine whether Significant Financial Interests could affect the design, conduct, or reporting of the research activities funded by PHS, or proposed for such funding, and determine what conditions or restrictions, if any, should be imposed by the institution to manage such interests. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interest include:

(1) public disclosure of significant financial interests;

(2) monitoring of research by independent reviewers;

(3) modification of the research plan;

(4) disqualification from participation in all or a portion of the research funded by the PHS;

(5) divestiture of significant financial interests; or

(6) severance of relationships that create actual or potential conflicts.

§ 50.606 Remedies.

(a) Each Institution that applies for research funding from the PHS must include in its policy for the identification and management of Significant Financial Interest procedures for enforcement action against employees who do not comply with the Institution's policy. If the failure of an employee to comply with the policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

(b) The HHS may inquire into the Institutional procedures and actions regarding financial interests in PHS-funded research, including the disposition of a particular financial interest. Such inquiry may be initiated based on information obtained by the HHS under this subpart, from an award-related document (application, progress report, publication of results), or any other source. Based on a specific inquiry, the HHS may decide that a particular Significant Financial Interest of the type described in § 50.606 will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed a Significant Financial Interest described in § 50.606 in accordance with this subpart. The PHS may determine that suspension of funding is necessary until the matter is resolved.

(c) In any case in which the Department determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a Significant Financial Interest that was not disclosed or managed as required by this subpart, the Institution must require disclosure of the financial interest in each public presentation of the results of the research.

§ 50.607 Other HHS regulations that apply.

Several other regulations and policies apply to this subpart. They include, but are not necessarily limited to:

42 CFR Part 50, Subpart D---Public Health Service grant appeals procedure

45 CFR Part 16---Procedures of the Departmental Grant Appeals Board

45 CFR Part 74---Administration of grants

45 CFR Part 76---Government-wide debarment and suspension (non-procurement)

45 CFR Part 92---Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments

2. A new Part 94 is added to 45 CFR to read as follows:

45 CFR Part 94---Responsible Prospective Contractors

94.1 Purpose.

94.2 Applicability

94.3 Definitions

94.4 Institutional Assurance and Responsibility regarding Significant Financial Interests of Investigators

94.5 Management of Significant Financial Interests

94.6 Remedies

Authority: 42 U.S.C. 216, 289b-1, 299c-3.

§ 94.1 Purpose.

This part promotes objectivity in research by establishing special standards for each Institution to ensure that the design, conduct, and reporting of research to be performed are not compromised by any Significant Financial Interest of an Investigator responsible for the design, conduct, or reporting of the research.

§ 94.2 Applicability.

This section is applicable to each Institution that seeks PHS funding for research and, through the implementation of this section, to each Investigator who participates in such research; provided that this section does not apply to SBIR Program Phase I applications.

§ 94.3 Definitions.

As used in this part:

"Contractor" means an entity that provides property or services for the direct benefit or use of the Federal Government.

"HHS" means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

"Institution" means any public or private entity or organization (excluding a Federal agency) (1) that submits a proposal for a research contract whether in response to a solicitation from the PHS or otherwise, or (2) that assumes the legal obligation to carry out the research required under the contract.

"Investigator" means the principal investigator and any other person at the Institution who is responsible for the design, conduct, or reporting of a research project funded by PHS, or proposed for such funding. For the purposes of the requirements of this section relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children.

"PHS" means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

"Public Health Service Act" or "PHS Act" mean the statute codified at 42 U.S.C. § 201 et seq.

"PHS Awarding Component" means an organizational unit of the PHS that funds research that is subject to this part.

"Research" means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this part, the term includes any such activity for which funding is available from a PHS Awarding Component, whether authorized under the PHS Act or other statutory authority.

"Significant Financial Interest" means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

- (1) salary, royalties, or other remuneration from the institution; or any ownership interests in the institution, if the institution is an applicant under the SBIR program;
- (2) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- (3) income from service on advisory committees or review panels for public or nonprofit entities; or
- (4) financial interests in business enterprises or entities if the value of such interests do not exceed \$5,000 or represent more than a five percent ownership interest for any one enterprise or entity when aggregated for the investigator and the investigator's spouse and dependent children.

"Small Business Innovation Research (SBIR) Program" means the extramural research program for small business that is established by the awarding components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this part, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

§94.4 Institutional Assurance and Responsibility regarding Significant Financial Interests of Investigators.

(a) Each Institution must:

(1) Inform each Investigator of the Institution's policy for identifying and managing Significant Financial Interests, the Investigator's reporting responsibilities, and of this part.

(2) Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

(3) Ensure that Investigators have provided to the designated official(s) a listing of Significant Financial Interests that ensures disclosure of all Significant Financial Interests of the type described in paragraph (e) (1) of this part, prior to the time an application is submitted to PHS. All financial disclosures must be updated during the pendency of the award, either on an annual basis, or as new reportable Significant Financial Interests are obtained.

(4) Provide guidelines consistent with this subpart for the designated official(s) to identify Significant Financial Interests of the type described in paragraph (e) (1) of this part and take such actions as necessary to ensure that any such financial interest will be managed, reduced, or eliminated.

(5) Maintain records identifiable to each award of all financial disclosures and all actions taken by the Institution with respect to each Significant Financial Interest of the type described in

§ 94.5 for at least three years beyond the termination or completion of the contract, or until resolution of any action by the HHS involving the records, whichever is longer.

(6) Establish procedures for resolving any alleged violation of the financial conflict of interest policy of the Institution and establish appropriate enforcement actions for failure to comply.

(7) Certify, in each contract proposal, that:

(i) there is in effect at that Institution a written and enforced administrative process to identify and manage, reduce or eliminate Significant Financial Interests of the type described in paragraph (e)(1) of this part with respect to all research projects for which funding is sought from the PHS,

(ii) the Institution either has, or has not found a Significant Financial Interest of the type described in paragraph (e)(1) of this part and, where such interest is found, certify that actions have been taken to manage, reduce or eliminate that interest in accordance with this part.

(iii) the Institution agrees to make information available, upon request, to the HHS regarding all Significant Financial Interests identified by the Institution of the type described in paragraph (e)(1) of this part and how those interests have been managed, reduced, or eliminated to protect the research from bias;

(iv) the Institution will otherwise comply with this part.

(8) (i) Notify the PHS Awarding Component of the identification and management, reduction or elimination of any Significant Financial Interest, of the type described in Sec. 94.5(a) of this Part that did not exist or was not known at the time of the proposal, within sixty days of its becoming aware of that Interest.

(ii) HHS may at any time request submission of, or review on site, all records pertinent to these certifications. To the extent permitted by law, the PHS will maintain all records of financial interests confidentially.

(iii) An investigator may participate in a PHS-funded research project that is being simultaneously supported by an organization that has a commercial interest in the outcome of the project. However, the research support must be provided through the PHS awardee Institution. Any direct compensation or payment to the Investigator under that support is considered a financial interest under this part.

§ 94.5 Management of Significant Financial Interests.

(a) Institutions seeking PHS funding for research shall ensure that the following types of Significant Financial Interests attributable to an Investigator are managed, reduced, or eliminated, in accordance with paragraph (b) of this section, prior to award of the contract:

(i) any Significant Financial Interest of the Investigator that would reasonably appear to be directly and significantly affected by the research funded by PHS, or proposed for funding; and

(ii) any Significant Financial Interest of the Investigator in an entity whose financial interest would reasonably appear to be directly and significantly affected by the research funded by PHS, or proposed for funding.

(b) In addition to the types of Significant Financial Interests described in this paragraph that must be managed, an Institution may require the management of other financial interests as the Institution deems appropriate.

(c) The designated official(s) must review all financial disclosures, determine whether Significant Financial Interests could affect the design, conduct, or reporting of the research activities funded by PHS, or proposed for such funding, and determine what conditions or restrictions, if any, should be imposed by the institution to manage such interests. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interest include:

- (1) public disclosure of significant financial interests;
- (2) monitoring of the research by independent reviewers;
- (3) modification of the research plan;
- (4) disqualification from participation in all or a portion of the research funded by the PHS;
- (5) divestiture of significant financial interests, or;
- (6) severance of relationships that create actual or potential conflicts.

§ 94.6 Remedies

(a) Each Institution that submits a research contract proposal must include in its policy for the identification and management of Significant Financial Interest procedures for enforcement action against employees who do not comply with the Institution's policy. If the failure of an employee to comply with the policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

(b) The HHS may inquire into the Institutional procedures and actions regarding financial interests in PHS-funded research, including the disposition of a particular financial interest. Such inquiry may be initiated based on information obtained by the HHS under this part, from a procurement-related document (proposal, progress report, publication of results) or any other source. Based on a specific inquiry, the HHS may decide that a particular Significant Financial Interest of the type described in section 4 of this part is so sensitive that the issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

(c) In any case in which the Department determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a Significant Financial Interest that was not disclosed or managed as required by this subpart, the Institution must require disclosure of the financial interest in each public presentation of the results of the research.

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NIH GUIDE, Volume 23, Number 25, July 1, 1994

P.T. 34; K.W. 1014006

National Institutes of Health

The following is a reprint of the Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research and Contracts, which was published in the Federal Register of June 27, 1994.

INTRODUCTION

The National Institutes of Health (NIH) is the principal biomedical and behavioral research agency within the Federal Government. Its mission is to improve human health by increasing scientific knowledge related to health and disease through the conduct and support of biomedical and behavioral research. The NIH advances its mission through intramural research activity and the award of research grants and contracts to institutions of higher education, research institutes and foundations, and other non-profit and for-profit organizations. Entities funded through NIH research grants, contracts, and cooperative agreements (hereafter collectively referred to as Grantees) are required to maximize the use of their research findings by making them available to the research community and the public at large and through their timely and effective transfer to industry for development.

In general, interactions between Grantees and industry take many forms, including industrial liaison programs, spinoff companies, consortia, commercial licenses, material transfers, consultations, and clinical trial agreements. This document addresses one form of Grantee/industry interaction, sponsored research agreements, on which the NIH has focused a substantial amount of its recent attention. Sponsored research agreements are agreements between Grantees and commercial entities in which Grantees receive funding or other consideration to support their research in return for preferential access and/or rights to intellectual property deriving from their research results.

In developing sponsored research agreements, Grantees must consider the Bayh-Dole Act of 1980 (1) (hereafter referred to as "Bayh-Dole" or "the Act") and NIH funding agreements and refrain from engaging in activities which undermine a Grantee's ability to fulfill its responsibilities and obligations to the Federal government. Although Grantees are primarily responsible for the implementation of the Act, NIH, as a steward of Federal funds, has a responsibility to provide guidance on issues regarding sponsored research agreements which may put Grantees at odds with the Act or NIH funding requirements.

PURPOSE

The purpose of this document is to provide Grantees with issues and points to consider in developing sponsored research agreements with commercial entities. The intent is to assist Grantees in ensuring that those agreements comply with the requirements of the Act and NIH funding agreements while upholding basic principles of academic freedom.

This document represents the culmination of various activities, under the aegis of the NIH Task Force on Commercialization of Intellectual Property Rights from NIH Supported Extramural Research, which included the review and analysis of 375 sponsored research agreements from 100 Grantees, meetings with industry, academia, and other Government agencies, and a specially convened public forum involving subject matter experts from outside of the NIH.

The NIH recognizes that sponsored research agreements are unique, creative devices which reflect the needs and interests of the parties involved and require a delicate balance of risks and benefits to all of the parties. Although this document identifies a number of points to consider, with some necessitating more scrutiny than others, no single point or issue is so dominant that it is likely to be fatal to an agreement. Rather, the juxtaposition of multiple factors or clauses in an agreement and their synergy needs to be assessed. Therefore, Grantees should review the provisions of proposed sponsored research agreements both individually and in their totality.

BACKGROUND

While NIH policies on the use of research results have been in effect for some time, commercial development of research results took a major step forward with the passage of the Bayh-Dole Act. Congress passed the Act in response to significant concerns about the United States' competitiveness and data indicating that rights to many inventions developed under Federal grants and contracts and assigned to the Federal government were not being commercialized. In general, the Act authorizes Grantees to retain title to inventions resulting from their Federally funded research and to license such inventions to commercial entities for development.

Specifically, the policy and objective of the Bayh-Dole are to:

- o Promote collaboration between commercial concerns and nonprofit organizations, including universities;
- o Promote the utilization of inventions arising from Federally supported research or development;
- o Encourage maximum participation of small business firms in Federally sponsored research and development efforts;
- o Ensure that inventions made by nonprofit organizations and small business firms are used to promote free competition and enterprise;
- o Promote the commercialization and public availability of inventions made in the United States by United States industry and labor;
- o Ensure that the Government obtains sufficient rights in Federally sponsored inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and
- o Minimize the costs of administering policies in this area.

The provisions of the Act have been implemented through regulations issued by the Department of Commerce and adopted by the Department of Health and Human Services.(2)

The Act serves the public not only by encouraging the development of useful commercial products such as drugs and clinical diagnostic materials, but also by providing economic benefits, and enhancing U.S. competitiveness in the global

Since its passage, the Bayh-Dole Act has been effective in promoting the transfer of technology from Grantees to industry as evidenced by the aggressive pursuit of patenting and licensing and the proliferation of university/industry collaborations (3). In addition, the development of many new and important drugs and devices have been facilitated by increased industrial support for academic research (4) and the explosion in the licensing of university owned inventions (5). Furthermore, statistics indicate that the Act has provided significant economic benefits which are projected as increasing between 25 to 30 percent per year (6).

GRANTEE RESPONSIBILITIES

In keeping with the objectives and policy of Bayh-Dole, it is incumbent upon Grantees to effectively and efficiently transfer technology to industry for commercial development. However, in doing so Grantees must also comply with the specific terms of the Act, its implementing regulations, and the terms and conditions of each NIH award and ensure that such compliance is reflected in their agreements with commercial entities.

In carrying out that responsibility, at a minimum, Grantees need to concern themselves with issues involving maintenance of academic freedom for institutions and investigators, fair access to information, timeliness of notification and other requirements, rational licensing to commercial entities, and adherence to the specific requirements of the Act and NIH funding agreements.

While sponsored research agreements frequently are used where basic research is involved and no invention exists to disclose nor intellectual property to license at the time the agreement is executed, Grantees should anticipate such issues to arise and use the following points for consideration in developing a sponsored research agreement.

The first section, Universal Points for Consideration, highlights several requirements and issues that Grantees should consider in all proposed sponsored research agreements. The second section, Points for Special Consideration, delineates circumstances which suggest heightened scrutiny. The third section, Other Points for Consideration by Non Profit Grantees, contains additional considerations which apply only to non profit Grantees.

UNIVERSAL POINTS FOR CONSIDERATION

Academic Freedom

Academic research freedom based upon social collaboration within the scientific community and the scrutiny of claims and beliefs by its members is at the heart of scientific advancement within the United States. Primarily through Federal funding, academic institutions have contributed to fundamental knowledge and techniques upon which current and future scientific discoveries and technological innovations depend. Therefore, the preservation of academic freedom for Grantee institutions and researchers is of considerable concern to the NIH.

Grantees should be aware that their interest in the scientific endeavor covered by a sponsored research agreement and the interest of the industrial sponsor may not be totally consonant. As a result, in general, Grantees should ensure that sponsored research agreements preserve the freedom for academic researchers to select projects, collaborate with other scientists, determine the types of sponsored research activities in which they wish to participate, and communicate their research findings at meetings, and by publication and through other means (7). Academic researchers also should be made aware of any agreements executed by their institutions which may restrict their ability to pursue research activities and publish research results. Grantees also should maintain their independence to pursue their own mission without undue influence or restraint by their industrial sponsors. For example, an agreement which gives an industrial sponsor the ability to direct the research mission of a Grantee would be inappropriate.

Dissemination of Research Results

Grantees must ensure that the timely dissemination of research findings is not adversely affected by the conditions of a sponsored research agreement. For example, the PHS Grants Policy Statement, incorporated as a condition of each NIH research grant, details policies on publication of research results, responsibilities to disseminate information on unique research resources, and standards of conduct for Grantee employees. Although an industrial sponsor's consideration of the commercial applicability of specific research findings and/or the filing of a patent application to secure intellectual property rights may justify a need to delay disclosure of research findings, a delay of up to thirty (30) days is generally viewed as a reasonable period for such activity. Depending upon the individual circumstances, Grantees could consider a shorter or longer period of time, as they deem appropriate. In addition to the timing, a sponsored research agreement which requires the disclosure of inventions and research findings developed with NIH funds to an industrial sponsor prior to submission of the invention disclosure to the NIH, may be inconsistent with the terms and conditions of the NIH grant or contract.

Utilization

The NIH also has a concern that Federally funded technology be developed and commercialized in an expedited and efficient manner. In deciding to enter into an agreement with an commercial entity, Grantees should consider whether the organization has the experience, capability, and commitment to bring its likely inventions to commercial status.

Additionally, Grantees should not enter into sponsored research agreements that permit a sponsor to tie up the development of a technology by acquiring exclusive licensing rights to the product of given research results before deciding whether or not it will actively develop and commercialize that product. Grantees should provide a sponsor with an option to pursue licensing rights. It is reasonable for such options to be limited to no more than six (6) months. However, individual circumstances may dictate a shorter or longer period of time. After the option period expires, the technology should become available for licensing to other entities. Moreover, once a sponsor decides not to exercise its option, it should not be given a second opportunity to obtain licensing rights by matching other parties' offers for the rights. Such requirements enable Grantees to license to companies presenting a bona fide commercialization plan, thus expediting the availability of products to the public.

In order to ensure that technology is developed rapidly and is not being subjected to delays, Grantees should also establish, maintain, and actively administer policies and procedures which ensure that licenses arising from sponsored research agreements contain due diligence requirements and benchmarks to monitor performance. When future rights to as yet undiscovered inventions are included in a sponsored research agreement, benchmarks for development of each such

invention should be established as it becomes available for commercial development. In addition, Grantees should actively monitor licensees in accordance with those requirements and benchmarks to assure compliance with Grantee obligations under the Act.

U.S. Manufacture

The Bayh-Dole Act requires that products developed with Federal funds and used and sold in the United States, be substantially manufactured here. In granting exclusive rights to use or sell any subject invention in the United States, Grantees must ensure that each agreement requires that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. In individual cases, a request for waiver may be considered by the NIH. A determination will be made based upon a showing by the Grantee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. In granting a waiver of the U.S. manufacture requirement, the NIH may consider other benefits conferred on the United States by the potential license including the rapid availability of a product of benefit to the health of the American people.

Notification Requirements and Records

In sponsored research agreements, as in other contexts, Grantees must also ensure that invention, patent and license notification requirements are adhered to in a timely manner. Timeliness considerations include prompt (1) employee notification to Grantee administrators of an invention made under NIH funding, (2) written disclosure to NIH of an invention and the intent to retain or convey to the Government title to the invention, (3) adherence to time frames for initial filing of patent applications in the United States and the filing of foreign patent applications, (4) execution and confirmation throughout the world of NIH license rights in the results of the research, and (5) notification to the NIH of any decision not to continue patent prosecution, pay fees, or defend the patent in reexamination.

Specifically, as conditions of NIH grants and cooperative agreements, Grantees must fully notify the NIH in a timely manner when an invention has been developed. In any event, disclosure to the NIH must be prior to the publication of any description of the invention. When applying for continued funding in each subsequent funding period, the institution must also provide either a listing of all inventions made during the preceding budget period or a certification that no inventions were made during the applicable period. A final invention statement and certification listing all inventions that were conceived or first actually reduced to practice during the course of work under the funding agreement is required within ninety (90) days following the expiration or termination of support on an applicable project. Additionally, Grantees need to adhere to the specific requirements contained in the patent clauses of their contracts as well as the general provisions of the Federal Acquisition Regulations.

Furthermore, Grantees must also document their compliance with the requirements of the Act, regulations, and terms and conditions of NIH awards, generally and as related to sponsored research agreements. Such Grantee records must be available for review by authorized Federal officials in accordance with the terms and conditions of the award. For example, concerning access and retention of records under NIH grants and cooperative agreements, regulations require grantees to retain financial and programmatic records, supporting documents, statistical records, and all other grantee records which may reasonably be considered pertinent to a grant or subgrant (8).

POINTS FOR SPECIAL CONSIDERATION

The NIH has identified several situations, outlined below, in which Grantees should exercise heightened sensitivity and scrutiny in the development of sponsored research agreements. Such an exercise should confirm that a sponsored research agreement does not adversely impact NIH funded activities and Grantee concerns such as academic freedom, or shift control of the Grantee's scientific activities, management, and independence into the hands of the sponsor. While there is no requirement that Grantees submit proposed sponsored research agreements to the NIH for review, at the discretion of the Grantee, the NIH may be consulted for additional clarification in instances where special considerations warrant.

First, Grantees should subject their sponsored research agreements to heightened scrutiny when one or more of the following threshold criteria apply:

- (a) the amount of financial support from the sponsor meets or exceeds \$5 million in any one year, or, \$50 million total over the total period of funding under the agreement;
- (b) the proportion of funding by the sponsor exceeds 20 per cent of the Grantee's total research funding;
- (c) the sponsor's prospective licensing rights cover all technologies developed by a major group or component of the Grantee organization, such as a large laboratory, department or center, or the technologies in question represent a substantial proportion of the anticipated intellectual output of the Grantee's research staff; or
- (d) the duration of the agreement is for 5 or more years.

If one or more of these criteria apply, it is more likely that the proposed sponsored research agreement will adversely affect open commercial access, especially for small businesses, to a Grantee's Federally funded research activities and may delay or impede the rapid development and commercialization of technology.

Second, Grantees should be concerned if the scope of the sponsored research agreement is so broad that the subsequent exclusive licensing of technology under the agreement provides a single sponsor with access to a wide array of Grantee research findings and technologies that effectively exclude other organizations from reasonable access to a Grantee's technology. This type of arrangement can also delay commercialization if the sponsor does not have the interest or the capability to develop the technology.

Third, if the sponsor contributes funds to support a Grantee's general operations rather than specifically defined research projects, the Grantee should consider the amount of the sponsor's general funding in relation to funds contributed from other sources when determining what prospective intellectual property rights the sponsor will receive in the results of the Grantee's entire research portfolio. There should be a reasonable relationship between the amount of money contributed by the sponsor and the rights that it is granted both to review and license resulting technology or inventions. As an extreme example, a sponsor should not be able to provide 5 percent of the Grantee's total support,

review 100 percent of the Grantee's inventions, and receive rights or a first option to 50 percent of the research results generated by the Grantee. Where general funding is involved, a Grantee should consider establishing some mechanism to limit the review and licensing rights of the sponsor to a particular segment or percentage of the inventions and for a set period of time. For example, the Grantee may require the sponsor to select those research areas or projects to which its general funding rights would attach in advance, thereby freeing up research areas that may be of interest to other commercial entities. Because, by its nature, general funding is less directed and its results more imprecise, Grantees should carefully monitor the impact on open competition and fair access by small business of the sponsor's licensing practices for technology supported by general funding.

Fourth, Grantees should avoid any other unusual practice or stipulation that might generate public concern or undermine rather than serve the public interest.

OTHER POINTS FOR CONSIDERATION BY NON-PROFIT GRANTEES

The following points are to aid non-profit Grantees in administering the Act and in complying with the requirements of NIH funding agreements.

First, Grantees must ensure that the rights to inventions resulting from Federal funding are not assigned without NIH approval. An exception to this is when the assignment is made to an organization which has as one of its primary functions the management of inventions, in which case, the assignee will be subject to the same provisions as the Grantee.

Second, Grantees must share royalties collected on NIH supported inventions with the inventors and the balance of any royalties or income earned, after payment of expenses, including payment to inventors and incidental expenses to the administration of subject inventions, must be utilized for the support of scientific research or education.

Third, Grantees must employ reasonable efforts to attract licensees of subject inventions that are small business firms. Additionally, Grantees must provide a preference to small business firms when licensing a subject invention if Grantees determine that small business firms have plans or proposals for marketing the invention which, if executed, are equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms. However, Grantees must be satisfied that the small business firms have the capability and resources to carry out plans or proposals. The decision whether to give a preference in any specific case is at the discretion of the Grantee. However, since sponsored research agreements typically provide exclusive licenses or options to such rights to the sponsor, Grantees should seriously consider and provide for these issues when negotiating such agreements.

CONCLUSION

Technology transfer is a vehicle through which the fruits of NIH funded research are transferred to industry to be ultimately developed into preventive, diagnostic and therapeutic products to advance human health. In a dynamic and multinational marketplace, if the United States is to remain a world leader in technological and scientific innovation, both the public and private sectors must work together to foster rapid development and commercialization of useful products to benefit human health, stimulate the economy, and enhance our international competitiveness, while at the same time protecting taxpayers' investment and safeguarding the principles of scientific integrity and academic freedom.

It is in this spirit that the NIH encourages Grantees to address the issues and apply the points for consideration identified in this document when developing sponsored research agreements with commercial entities.

INQUIRIES

Comments or inquiries may be directed to:

Mr. Theodore J. Roumel
Office of Science Policy and Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852-3804
Telephone: (301) 496-7057 ext. 203
FAX: (301) 402-0220

FOOTNOTES

1. Public Law 96-517, enacted December 12, 1980, Chapter 38--Patent Rights in Inventions Made with Federal Assistance.
2. The Department of Commerce regulations are at 37 Code of Federal Regulations (CFR) Part 401 and supersede applicable portions of 45 CFR Parts 6 and 8.
3. Approximately one in every four university patents issued in the late 1980s was for a biomedical or health related invention. In the early 1970s, the ratio was one in eight. Source: Science and Engineering Indicators, 1993, National Science Foundation.
4. While still representing less than 10 percent of the total funding for academic research, it is estimated that nearly two percent of United States industry's expenditures for R&D now goes to academic institutions, as compared with less than 1 percent in 1971. Source: Science and Engineering Indicators, 1993, National Science Foundation.
5. Over 1000 licenses or options were executed in Fiscal Year 1992 by 260 academic institutions surveyed. The institutions also reported that they had over 5000 active licenses in place at the time of the survey. Source: Association of University Transfer Managers Licensing Survey FY 1991-1992, published October, 1993.
6. In FY 1992 sales and employment attributable to the Act were estimated to be as follows: between \$9 and \$13 billion in sales and 50-100,000 jobs, with an annual increase of between 25 and 30 percent. Source: Dr. Ashley J. Stevens, Director, Office of Technology Transfer, Dana-Farber Cancer Institute, Association of University Technology Managers

7. The NIH recognizes that there may be certain instances when it may be reasonable for a Grantee institution to agree to minimally restrict a researcher from collaborating with another industrial partner when the subject matter of such collaboration overlaps with that of the sponsored research agreement.

8. The regulations are set forth at 45 CFR Part 74, Subpart D and 45 CFR Part 92.42.

REINVENTION ACTIVITIES

NIH GUIDE, Volume 23, Number 25, July 1, 1994

P.T. 34; K.W. 1014006

National Institutes of Health

Recently, the NIH extramural programs were designated a Public Health Service "Reinvention Laboratory." A number of reinvention activities have been undertaken to make the NIH work better and cost less. These activities are, in part, a continuation of the usual reevaluation of policies and procedures, which is even more critical now because of fiscal constraints on both the NIH and research institutions. An important goal of this effort is to decrease the workload of applicants and reviewers while conserving resources for the direct support of research.

PEER REVIEW

In one set of activities, NIH is examining ways to streamline peer review. The number of applications reviewed by NIH has increased from fewer than 19,000 in 1983 to more than 38,000 in 1993. Neither staffing nor funding have kept pace with this increase. The fair review of all applications is the guiding principle and any change considered will uphold that principle.

The use of triage for the review of applications received in response to RFAs has been evaluated and found to be both effective and fair. Now, the value of triage in the review of investigator-initiated applications is being assessed. The comments of reviewers and a careful evaluation of outcome are vital components of the study.

A pilot study of the triage of grant applications extends the use of triage from the institutes to the Division of Research Grants (DRG). Reviewers designate the least meritorious applications "noncompetitive" and provide scores for only those applications considered clearly "competitive" for funding. It is important to note that "non-competitive" should not be equated with either the previously used "disapproval" or presently used "not recommended for further consideration" categories. The pilot study of the triage process is an attempt to reduce the workload of the researchers who serve on study sections and allow more discussion of the applications that are considered competitive.

The first phase of the triage pilot study, conducted by selected Study Sections within the DRG during the February, 1994 review round, incorporated a streamlined format for the expedited production of summary statements. Thus, the critiques of "non-competitive" applications consisted of essentially unabridged comments from the reviewers and could be sent to applicants almost immediately following the meeting of the Study Section, providing the applicant more time to amend and resubmit the application. An expanded pilot study, taking into consideration the comments of participants in the initial study, is being conducted in the June, 1994 review round. In this study, streamlined summary statements will be used for all applications. For the group of "competitive" applications, the document will also contain a "Resume and Summary of Discussion" to convey the highlights of the discussion at the study section meeting and a paragraph detailing the budgetary recommendations.

Another initiative addresses the desirability of having reviewers place greater emphasis on the person being supported than on the specifics of a project. For example, the extension of MERIT awards emphasizes retrospective evaluation of the investigator whereas the traditional R01 review focuses on a prospective review of planned activities. The most appropriate balance between these two perspectives is one topic of discussion.

Within DRG, a study will soon be undertaken to assess the effectiveness of automatically assigning competing renewal and amended applications to the Institute or Center (IC) and Initial Review Group of the previous record. While deviations could, of course, occur, it may be desirable to ensure that applicants, program staff, and review administrators are clear about the standard procedures.

STRUCTURE OF AWARDS

A number of initiatives related to the research grant programs are also under consideration or soon to be initiated. For example, there has been discussion of establishing modular grants, at levels of support preset by NIH (e.g., \$150,000, \$250,000). This could be combined with an assurance that subsequent budget reductions would be very unlikely or paylines set by size of grant such that the payable for smaller awards would be higher than that for larger.

GRANT APPLICATION

Another set of reinvention activities focuses on reducing the burden of providing grant application material. The "just-in-time" pilot test postpones the collection of a fairly substantial amount of information that currently must be provided in all competing applications until an application clearly is being considered for funding. This delayed request and receipt of information relieves the burden for approximately 70 to 75 percent of applicants who will not receive an award. The information that would be delayed or simplified includes the collection of other support information, specific budget detail, and the biographical sketch. The biographical sketch will include only information related to research background and experience, including, at the option of the applicant, the other support relevant to the proposed research. If relevant support is cited, only the title and source is necessary. This approach may simplify and reduce the administrative burden associated with the NIH grant application without compromising the initial review group determination of scientific merit or the reasonableness of the proposed budget. Information relevant to the award of the project would be exchanged "just in time" prior to award.

"Just-in-time" is being studied through four RFAs from four ICs. This provides an opportunity to explain the requirements to a defined set of applicants and to evaluate the results. As with many such innovations, the effect may be beneficial for some (applicants who are not funded) and not for others (grants administration staff). It is essential that the applicant Principal Investigator and institution can provide the detailed information quickly if a decision is made to fund an application.

ELECTRONIC RESEARCH ADMINISTRATION

The electronic exchange of application and post-award information has been assigned high priority. A proposal for Electronic Research Administration (ERA) is being drafted. Within this system, each institution would use a unique, assigned number to submit applications, and institutional information would then be drawn automatically from a database of complete institutional profiles. Thus, the need to provide data repeatedly on a project-by-project basis would be eliminated. In addition, electronic application files would be created to serve as the repository for all information generated during the life cycle of each project. This data base would be accessible to authorized institutional and NIH staff, who could each review and add information as required.

INFORMATION ABOUT EXTRAMURAL RESEARCH PROGRAMS

High priority is also assigned to increasing electronic availability of information about extramural research programs. Currently, the research community can access the NIH Guide for Grants and Contracts and telephone directory on both the NIH Gopher and NIH Grantline; the PHS Grants Policy Statement on the NIH Grantline; and the (CRISP) database, which lists all NIH grant and contract awards, on the NIH Gopher. The full text of the NIH Guide and the Table of Contents is available through separate LISTSERV subscriptions (NIH Guide, Vol. 23, No. 20, May 27, 1994). Information from the Office for Protection from Research Risks (OPRR); rosters of advisory groups including review groups; the minutes of the National Advisory Council meetings; the NIH Extramural Programs; and descriptions of ongoing programs such as the First Independent Research Support and Transition (FIRST) Awards and the National Research Service Act (NRSA) Awards will be available electronically in the future.

NATIONAL PERFORMANCE REVIEW

In addition to the projects outlined above, several reinvention activities are being explored to manage the reduced Federal workforce mandated by the National Performance Review. Among them is the increased use of the Intergovernmental Personnel Act (IPA), which permits Federal agencies to obtain the services of experts from eligible institutions. This could offer valuable opportunities for extramural scientists in emerging areas of science to gain exposure to the NIH extramural processes and transfer that knowledge to their home institutions.

Several other initiatives, selected for the potential to improve service to the research community and increase administrative efficiency, are in the very early stages of development. Some involve administrative simplifications that can be implemented immediately; others will require further evolution before they can be initiated in the short or long term. All are part of an ongoing process being conducted with broad involvement across the NIH and in partnership with the greater scientific community.

INQUIRIES

Researchers and members of all segments of the extramural research community are encouraged to contribute suggestions for additional modifications of NIH procedures and comments on the ongoing activities. Comments may be sent to:

Dr. Wendy Baldwin
Deputy Director for Extramural Research
National Institutes of Health
Building 1, Room 144
Bethesda, MD 20892
e-mail: lef@cu.nih.gov

AVAILABILITY OF DATA ON AGING

NIH GUIDE, Volume 23, Number 25, July 1, 1994

P.T. 34; K.W. 0710010, 0755018, 0404021

National Institute on Aging

PURPOSE

The following program announcements were previously published in the NIH Guide: The Oldest Old (Vol. 17, No. 18, May 20, 1988); Economics of Aging, Health, and Retirement (Vol. 20, No. 15, Apr 12, 1991); Special Emphasis Research Career Award: The Demography and Economics of Aging (Vol. 20, No. 17, Apr 26, 1991); Forecasting Life and Health Expectancy in Older Populations (Vol. 20, No. 34, Sep 13, 1991); Causes and Effects of Elderly Population Concentrations (Vol. 21, No. 12, Mar 27, 1992); and Medical Demography of Dementias of Aging (Vol. 21, No. 24, Jun 26, 1992). As an update to these program announcements, data from several sources supported by the National Institute on Aging are available. These include, but are not limited to, the Health and Retirement Study; Longitudinal Study of Aging; the Supplement on Aging II, National Long-Term Care Survey: 1982-1989; National Longitudinal Survey: 1990 Resurvey of Older Males; National Nursing Home Survey Followup; and Panel Study of Income Dynamics. These data are public use files designed to be used for secondary data analysis. Public use files from the Wisconsin Longitudinal Study, the Asset and Health Dynamics of the Oldest-Old, and the National Survey of Families and Households Reinterview are expected to be available by the Fall of 1994. The National Institute on Aging encourages low cost applications based on secondary analysis of data sources on the elderly.

INQUIRIES

Written inquiries regarding the description of and access to these data files may be directed to:

Georgianne E. Patmios
Behavioral and Social Research Program
National Institute on Aging
7201 Wisconsin Avenue, Room 533
Bethesda, MD 20892
PATMIOS@NIHNIAGW.Bitnet

Written inquiries regarding programmatic issues may be directed to:

Richard Suzman
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National Institute on Aging
7201 Wisconsin Avenue, Room 533
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NOTICES OF AVAILABILITY (RFPS AND RFAs)

CORE GRANTS FOR CLINICAL NUTRITION RESEARCH UNITS

NIH GUIDE, Volume 23, Number 25, July 1, 1994

RFA AVAILABLE: DK-94-019

P.T. 04; K.W. 0710095, 0785035

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: October 21, 1994

Application Receipt Date: November 22, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites applications for funding of two Clinical Nutrition Research Unit (CNRU) grants to be competitively awarded in Fiscal Year 1996.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Core Grants for Clinical Nutrition Research Units, is related to the priority areas of nutrition, physical activity and fitness, heart disease and stroke, cancer, diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Minority individuals and women are encouraged to submit as principal investigators. Foreign institutions are not eligible to apply.

MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health (NIH) core center (P30) award. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the PHS Grants Policy Statement. The earliest anticipated award date will be December 1, 1995.

FUNDS AVAILABLE

The NIDDK anticipates awarding two CNRU Grant in Fiscal Year 1995 on a competitive basis. The receipt of two competing continuation applications is anticipated, which will be in competition with other applications received in response to this RFA. The anticipated awards will be for five years and will be contingent upon the availability of appropriated funds. Requests for support must be limited to no more than \$700,000 direct costs per year. Any application exceeding this amount will be returned to the applicant.

RESEARCH OBJECTIVES

The NIDDK-supported CNRUs are part of an integrated program of nutrition and obesity-related research support provided by the NIDDK. These centers have provided a focus for increasing collaboration and cost effectiveness among groups of successful investigators at institutions with established comprehensive nutritional sciences and obesity research bases.

The objectives of the CNRUs are to bring together investigators from relevant disciplines in a manner that will enhance and extend the effectiveness of research related to the nutritional sciences, obesity, and related disorders. Applicants should consult with NIDDK staff concerning plans for the development of the center.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by October 21, 1994, a letter of intent, that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows ICD staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Review Branch
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 603
Bethesda, MD 20892

APPLICATION PROCEDURES

Applications are to be submitted using form PHS 398 (rev. 9/91), available in the office of sponsored research at most academic or research institutions and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. The RFA label available in the PHS 398 application form must be affixed to the bottom of the face page.

Applications must be received by November 22, 1994, the original and three copies of the application must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Two additional copies of the application under separate cover must be sent to the Review Branch at the address listed under LETTER OF INTENT.

REVIEW CONSIDERATIONS

Applications for a CNRU grant will be evaluated in competition by the NIH grant peer review process. Applications will be reviewed initially by an ad hoc review group convened by the NIDDK and subsequently by the National Diabetes and Digestive and Kidney Diseases Advisory Council.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Applicants should request a copy of "Guidelines for Clinical Nutrition Research Units." These guidelines contain important additional information of the format, content and review criteria. Prospective applicants may obtain guidelines from and address inquiries to:

Van S. Hubbard, M.D., Ph.D.
Division of Digestive Diseases and Nutrition
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A18B
Bethesda, MD 20892
Telephone: (301) 594-7573
FAX: (301) 594-7504

Inquiries regarding fiscal matters may be directed to:

Ms. Trude McCain
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 653
Bethesda, MD 20892
Telephone: (301) 594-7543

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.847. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

STRATEGIC PROGRAM FOR INNOVATIVE RESEARCH ON AIDS TREATMENT

NIH GUIDE, Volume 23, Number 25, July 1, 1994

RFA AVAILABLE: AI-94-026

P.T. 34; K.W. 0715008, 0765014, 0745045, 1002045

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: September 20, 1994
Application Receipt Date: December 8, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID), invites applications from a combination of academic, non-profit research, and commercial organizations dedicated to expedite ground-breaking research from advanced preclinical stage to pilot clinical studies in HIV-infected individuals. Research activities can focus on viral gene(s) and/or cellular factors required for HIV expression, novel immunotherapeutic approaches, or other unique therapeutic strategies. Studies supported by this RFA may have greater conceptual risk than currently exercised for treating HIV-infected individuals, but are also expected to have greater potential for effective, long-term therapeutic returns. The objective of this RFA is to support innovative, integrated preclinical and clinical research to validate clinical therapeutic concepts for the treatment of HIV-1 infection. Therapies based on anti-HIV drugs or on opportunistic pathogens associated with AIDS are supported by other NIAID programs and are excluded from this RFA.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Strategic Program for Innovative Research on AIDS Treatment (SPIRAT), is related to the priority area of HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged. Applications from foreign institutions will be considered.

The administrative and funding mechanism to be used to undertake this program will be the cooperative agreement (U19), an "assistance" mechanism, rather than an "acquisition" mechanism, in which substantial NIH scientific and/or programmatic involvement with the awardee is anticipated during the performance of the activity. Essential elements of the U19 mechanism include: (1) a minimum of three interrelated research projects organized around a central theme for the entire duration of the award; (2) collaborative efforts and interaction among independent projects and their investigators to attain a common goal; (3) a single Principal Investigator who will be scientifically and financially responsible for the use and disposition of funds awarded; and (4) "Core" resources, each expected to be utilized by at least two research projects. Details of the responsibilities, relationships, and governance of a study funded under cooperative agreement(s) are discussed in the RFA under the section Terms and Conditions of Award. The total project period for an application may not exceed four years. Anticipated award date is August 1995.

FUNDS AVAILABLE

The estimated total funds (direct and indirect costs) available for the first year of support for awards under this RFA reissuance will be \$2.5 million; estimated total project costs (direct and indirect) over the four-year period will be \$10.6 million. Applications in excess of \$1.3 million first year total cost (direct and indirect) will be returned without review. In Fiscal Year 1995, the NIAID plans to fund at least two new SPIRAT groups. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit.

RESEARCH OBJECTIVES

The purpose of this RFA is to support advanced preclinical studies and clinical proof-of-concept of innovative strategies and immunotherapy for the treatment of HIV disease. The principal objectives of this RFA are to (1) tightly couple innovative preclinical research with clinical proof-of concept; and (2) implement pilot clinical studies of a therapeutic strategy in HIV-infected individuals. Applicants for this RFA will already have an identified strategy that is based on creative and solid scientific rationale, and for which advanced preclinical data exist. These efforts are to be implemented through a concerted and interdependent activities by components constituting the group. The following approaches are provided as examples and are not intended to be inclusive or restrictive:

- o Strategies that interfere with HIV gene expression via viral regulatory elements, cellular factors, HIV/cell interaction, and novel approaches unlikely to be affected by emergence of resistant HIV variants;
- o Therapeutic strategies that integrate current understanding of HIV accessory proteins;
- o Intracellular delivery of genetic antagonists to curb pivotal events in HIV life cycle using ex vivo and in vivo delivery strategies;
- o Immune system reconstitution, including infusion of genetically modified lymphocytes, hematopoietic stem cells, xenogeneic transplantation;
- o Strategies that target non-T cells (dendritic cells, follicular dendritic cells, monocyte/macrophage, epithelial) believed to play an essential role in cell-free virus transport, trapping, and cell-cell transmission;
- o Genetic immunization to augment immune response(s) via intracellular expression of HIV immunogen(s);
- o Cell or tissue based approaches designed to modulate or curtail the pathogenic course of infection;
- o Strategies that target the central nervous system and have the potential to prevent or reverse AIDS-related neurologic dysfunction and dementia
- o Innovative therapeutic strategies that address pediatric HIV disease and pathogenesis.

Exclusions: studies involving anti-viral drugs, therapies involving the use of monoclonal antibodies, and opportunistic infections associated with AIDS are not supported by this RFA.

SPECIAL REQUIREMENTS

Applicants for SPIRAT funding must have an identified therapeutic strategy that is proposed for pilot clinical evaluation, and for which advanced preclinical data already exist. The proposed strategy must be sufficiently advanced and adequate to permit initiation of pilot clinical studies within two years of funding. All applications must consist of at least three interrelated and interdependent projects focusing on a unifying central theme conducted by at least three independent laboratories. For the purpose of encouraging new collaborations under this RFA, two (or more) projects within a single company will not be considered independent. Similarly, two (or more) projects within the same academic department will not be considered independent. A minimum 20 percent (time) effort by the Principal Investigator and each Project Leader should be devoted to the study. Applications with less than 20 percent efforts which do not offer compelling arguments for failing to comply with the 20 percent requirement will be considered non-responsive and will be returned to the applicant without review.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research" (NIH Guide Vol. 23 No. 11, March 18, 1994). See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by September 20, 1994, a letter of intent that includes a descriptive title of the overall proposed research, the name, address and telephone number of the Principal Investigator, the number and title of this RFA, and a list of the key investigators and their institution(s) and projects. The letter of intent is to be sent to Dr. Dianne Tingley at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted on the standard research grant application form PHS 398 (rev. 9/91). These application forms may be obtained from the institution's office of sponsored research or its equivalent, and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. For purposes of identification and processing, item 2a on the face page of the application must be marked "YES" and the RFA number and the words "STRATEGIC PROGRAM FOR INNOVATIVE RESEARCH ON AIDS TREATMENT (SPIRAT)" must be typed in. Applications must be received by December 8, 1994.

REVIEW CONSIDERATIONS

All applications will be judged on the basis of the scientific and technical merit of the proposed projects and the documented ability of the investigators to meet the RESEARCH OBJECTIVES of the RFA. Applications with first year total costs (direct and indirect) in excess of \$1.3 million will be returned without review. Applications will also be reviewed for complying with the minimum requirements described in the SPIRAT RFA. Those not meeting all the requirements will be considered not responsive and will be returned without further review. Applications that are complete and responsive may be subjected to a triage by a peer review group to determine their scientific merit relative to other applications received. The NIAID will withdraw from further competition those applications judged to be noncompetitive for award and will notify the Principal Investigator and institutional business official.

AWARD CRITERIA

Award criteria will be made on the basis of scientific and technical merit as determined by peer review, program needs and balance, and the availability of funds.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify issues or questions about the RFA from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Nava Sarver, Ph.D.
Division of AIDS
National Institute of Allergy and Infectious Diseases
Solar Building, Room 2C-11
Bethesda, MD 20892
Telephone: (301) 496-8197
FAX: (301) 402-3211

Direct the letter of intent and inquiries regarding application preparation and review to:

Dianne Tingley, Ph.D.
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C16
Bethesda, MD 20892
Telephone: (301) 496-0818
FAX: (301) 402-2638

Direct inquiries regarding fiscal matters to:

Ms. Pamela Greenwald
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B22
Bethesda, MD 20892
Telephone: (301) 496-7075
FAX: (301) 480-3780

AUTHORITY AND REGULATIONS

This program is described in the catalog of Federal Domestic Assistance, 93.856 - Microbiology and Infectious Diseases Research and 93.855 - Immunology, Allergy and Transplantation Research. Awards are made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 122372 or Health Systems Agency review.

HEALTH SERVICES RESEARCH ON CLINICAL PREVENTIVE SERVICES

NIH GUIDE, Volume 23, Number 25, July 1, 1994

PA NUMBER: PA-94-076

P.T. 34; K.W. 0730050, 0404003, 0745027, 0715148

Agency for Health Care Policy and Research
National Institute on Alcohol Abuse and Alcoholism
National Institute on Dental Research

The following is an addendum to PA-94-076, which was published in the NIH Guide for Grants and Contracts, Vol. 23, No. 24, June 24, 1994.

Under the RESEARCH OBJECTIVES, replace the section Research Interests of the NIDR with the following:

Under the general framework of this PA, NIDR invites applications for research in which the primary dependent variable of interest is a measure of oral diseases (e.g., caries, periodontal diseases, acquired or congenital craniofacial anomalies, orofacial growth abnormalities, salivary dysfunctions, oral cancers, oral manifestations of HIV infection, oral soft tissue disorders, oral sensory disorders, oral motor disorders, and acute or chronic orofacial pain conditions, including temporomandibular disorders).

Preventive interventions of interest include, but are not limited to, the use of sealants, fluoride supplements, antimicrobials, plaque-disclosing agents, nutritional supplements to prevent craniofacial anomalies or oral bone loss, innovative approaches to delivering preventive dental services to high-risk populations, cost-effective approaches for integrating preventive interventions for dental disorders and systemic health conditions, and innovative approaches for intercepting growth abnormalities or the development of chronic orofacial pain conditions, including temporomandibular disorders.

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

5333 Westbard Avenue
Bethesda, MD 20816

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For Grants and Contracts

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JUL 25 1994

National Institutes of Health

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 26
July 15, 1994

RICHARD W MURRY

* 340189
S1350E

929 WILD FOREST DRIVE
GAITHERSBURG MD 20879 3209

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

THE PUBLIC HEALTH SERVICE (PHS) STRONGLY ENCOURAGES ALL GRANT RECIPIENTS TO PROVIDE A SMOKE-FREE WORKPLACE AND PROMOTE THE NON-USE OF ALL TOBACCO PRODUCTS. THIS IS CONSISTENT WITH THE PHS MISSION TO PROTECT AND ADVANCE THE PHYSICAL AND MENTAL HEALTH OF THE AMERICAN PEOPLE.

PUBLIC HEALTH SERVICE POLICY RELATING TO DISTRIBUTION OF UNIQUE RESEARCH RESOURCES PRODUCED WITH PHS FUNDING

NIH GUIDE, Volume 23, Number 26, July 15, 1994

P.T. 36; K.W. 0780010

Public Health Service

This announcement is a republication of the one last appearing in the NIH Guide for Grants and Contracts, Vol. 21, No. 33, September 11, 1992.

Investigators conducting biomedical research frequently develop unique research resources. Categories of these resources include: synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data. Some specific examples are: specialized and/or genetically defined cell lines, including normal and diseased human cells; monoclonal antibodies; hybridoma cell lines; microbial cells and products; viruses and viral products; recombinant nucleic acid molecules; DNA probes; nucleic acid and protein sequences; certain types of animals such as transgenic mice; and intellectual property such as computer programs. The PHS provides the following statement of policy concerning unique research resources developed through PHS awards.

A. Policy on Distribution of Research Resources

The policy of the PHS is to make available to the public the results and accomplishments of the activities that it funds. Restricted availability of unique resources upon which further studies are dependent can impede the advancement of research and the delivery of medical care. Therefore, when these resources are developed with PHS funds and the associated research findings have been published or after they have been provided to the agencies under contract, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. This policy applies to PHS intramural investigators as well as extramural scientists funded by PHS grants, cooperative agreements, and contracts.

Because of concern that some crystallographers are not making their coordinates available promptly (see Science, Vol. 245, p. 1179), one of the national advisory councils of the NIH and the executive committee of another institute recently adopted resolutions affirming the policy of the International Union of Crystallographers (IUCr) (Acta Cryst., A45: 658, 1989). The PHS has now adopted the IUCr policy that includes data from publications based on spectroscopic data such as nuclear magnetic resonance as well as crystallographic coordinates.

The PHS encourages investigators who have such resources to consult the appropriate Program Administrators who may be of assistance in determining a suitable distribution mechanism. Such a mechanism should take into consideration all applicable Federal regulations including, but not limited to: those regarding human subjects, animal welfare, and use and handling of hazardous materials, where applicable. Investigators requesting materials should provide evidence of having the proper training, experience, and facilities to make use of the items they request. Program staff of the agencies will be available to assist in verification of credentials of requesters where such concern exists on the part of suppliers.

Investigators who believe that they will be unable to implement this policy should promptly contact the appropriate PHS Program Administrator to discuss the circumstances, obtain information that might facilitate compliance with the policy, and reach an understanding in advance of the subsequent award. For research and development contracts, approval should be obtained from the PHS Contracting Officer before distribution of unique resources, unless the terms of the contract permit distribution without prior clearance of the Contracting Officer. In order to facilitate the availability of unique or novel biological materials and resources developed with PHS funds, investigators may distribute the materials through their own laboratory or institution or submit them, if appropriate, to entities such as the American Type Culture Collection or other repositories. In the case of unique biological information, such as DNA sequences or crystallographic coordinates, investigators are expected to submit them to the appropriate data banks because they otherwise are not truly accessible to the scientific community. When distributing unique resources, investigators are to include pertinent information on the nature, quality, or characterization of the materials.

Investigators must exercise great care to ensure that resources involving human cells or tissues do not identify original donors or subjects, directly or through identifiers, such as codes linked to the donors or subjects.

The goals of some programs, (e.g., the Human Genome Program) are such that applicants for certain projects may be required to provide plans for the sharing of data and materials. These plans will undergo review by program staff and the national advisory council prior to award.

B. Distribution Costs

Institutions and investigators may charge the requester, if necessary, for the reasonable cost of production of unique biological materials, and for packaging and shipping. Such costs may include labor, supplies, and other directly related expenses. Investigators should note, however, that such a charge accrues as general program income. This should not be an impediment to the distribution of materials, but investigators and institutions are advised that:

a) for grants, the income is governed by 45 CFR Part 74 and it must be reported on the Financial Status Report. Questions regarding these policies and the treatment of income should be directed to the Grants Management Officer.

b) for contracts, the income is governed by Federal Acquisition Regulations (FAR) 45.610-3. Contracting Officers must be contacted before generating any revenues from the distribution of materials. Any contract under which research resources would be sold require specific contract instructions. Existing contracts may require an amendment and specific approval of the Contracting Officer to render them allowable.

Federal policy encourages the commercialization of the products of research developed as a consequence of Federal funding; therefore, the intent of this policy is to not discourage, impede, or prohibit the organization that develops unique research resources or intellectual property from commercializing the products. Investigators may make their materials available to others for commercial purposes with appropriate restrictions and licensing terms as they and their institution deem necessary.

Institutions are reminded that some of these products may be inventions subject to the various laws and regulations applicable to patents and must be reported to the Extramural Inventions Reports Office of the NIH. The terms for licensing of unpatented research products, such as cell lines, monoclonal antibodies, and other materials and products, should generally be no more restrictive than would have been the case had they been patented---for example, only if there is full public disclosure of the invention/discovery, availability through a repository, and written agreement to end all fees and constraints after 17 years. When reporting is required, it should occur at the earliest possible time. (See 37 CFR 401 and NIH Guide for Grants and Contracts, Vol. 19, No. 6, February 9, 1990.)

NIH MIDWEST REGIONAL SEMINAR IN PROGRAM FUNDING AND GRANTS ADMINISTRATION

NIH GUIDE, Volume 23, Number 26, July 15, 1994

P.T. 34; K.W. 1014006

National Institutes of Health

A regional seminar covering topics related to program funding and grants administration at the National Institutes of Health (NIH) has been scheduled for July 21-22, 1994. The seminar, hosted by Northwestern University and held on its Evanston campus, is intended to attract faculty and research administrators from the midwest region of the United States, although those interested from other regions are also invited and welcome. Staff from small and minority colleges, for-profit research organizations, hospitals, universities, and medical centers are encouraged to attend.

This two-day seminar will have a dual focus of interest to both academic researchers, as well as new and senior research administrators. Discussions of current issues that affect NIH funding and grants administration will be featured to give conference participants a comprehensive view of NIH-sponsored research. There will be time available to network with fellow researchers and meet informally with NIH representatives to discuss topics of special interest.

Mr. Geoffrey Grant, Acting Director, NIH Office of Policy for Extramural Research Administration, and outstanding representatives from the Grants Policy Office, Division of Research Grants, and several awarding components of the NIH will be featured speakers.

SEMINAR LOGISTICS

Seminar Leader:
Geoffrey Grant, Acting Director
Office of Policy for Extramural Research Administration (OPERA)

Seminar Coordinator (NIH):
Joellen M. Harper, NIH Grants Policy Office, 301/496-5967

Seminar Coordinator (Northwestern):
Barbara Siegel, Office of Research and Sponsored Programs,
Northwestern University, 708/491-3003

Dates: Thursday and Friday, July 21-22, 1994

Location: Northwestern University, Evanston, Illinois

Cost of Workshop: \$100

REGISTRATION AND INQUIRIES

Advance registration is required by July 12, 1994. You are encouraged to register early, because conference space is limited to the first 300 registrants. For registration materials, send a FAX that provides your name, institution, address, telephone number, and anticipated number of registrants to Ms. Barbara Siegel, 708/491-4800. Individuals who previously asked to be placed on the mailing list for registration materials will receive them automatically. It is not necessary to request them again.

FUTURE SEMINARS

A SOUTHWEST SEMINAR will be hosted by the University of New Mexico in Albuquerque, New Mexico, November 17-18, 1994. To request registration materials, call 505/277-3942 or send a FAX that provides your name, institution, address, telephone number, and anticipated number of registrants to 505/277-8604. Registration materials will be finalized and mailed two to three months before the seminar.

At this time, the dates and locations for regional seminars to be held in 1995 have not been finalized. If you have any questions about hosting a regional seminar, contact Ms. Joellen Harper in the NIH Grants Policy Office on 301/496-5967.

NATIONAL ANIMAL WELFARE EDUCATION WORKSHOP

NIH GUIDE, Volume 23, Number 26, July 15, 1994

P.T. 42; K.W. 0201011, 1014003

National Institutes of Health

The National Institutes of Health (NIH), Office of Extramural Research (OER), Office for Protection from Research Risks (OPRR) is cosponsoring a National Animal Welfare Education Workshop with The Department of Veterans Affairs. The workshop is open to all persons involved in the management and/or oversight of an institutional animal care and use program including institutional administrators, members of Institution Animal Care and Use Committees, laboratory animal veterinarians, investigators, and technicians.

DATES: August 4-5, 1994

TOPIC: Sharing Animal Welfare Responsibilities Between Affiliated Institutions

LOCATION

Portland Marriott Hotel
1401 SW Front Avenue
Portland OR
Telephone: (503) 226-7600 or 1-800-228-9290

SPONSOR

Department of Veterans Affairs

REGISTRATION

Ms. Margaret Doherty
Department of Veterans Affairs Medical Center
Veterinary Medical Unit (151-2)
3710 SW U.S. Veterans Hospital Road
Portland OR 97201
Telephone: (503) 220-8262 Ext. 7610
FAX: (503) 273-5351

FEE: \$150 - Regular; \$100 - Students and Technicians - Registration fee includes workshop materials, two continental breakfasts, one lunch, one wine and cheese social, and refreshment breaks.

DESCRIPTION: The workshop will explore the relationships among Academic, Government, and Industry as they pertain to the care and use of laboratory animals and animal research facilities and programs. The speakers will focus on issues such as assuming responsibility; VA vs. Academia; building shared institutional animal care and use committees; proprietary information; and the regulatory agencies' perspective and oversight.

DATES: SEPTEMBER 29-30, 1994

TOPIC: Use of Animals in Research and Alternatives

LOCATION: The Monteleone Hotel, New Orleans, LA

SPONSORS

Louisiana State University Medical Center
Xavier University of Louisiana

REGISTRATION

Ms. Lois Herbez
Louisiana State University Medical Center
1542 Tulane Avenue
New Orleans, LA 70112
Telephone: (504) 568-4198
FAX: (504) 568-4843

FEE: \$150

DESCRIPTION: The theme of the workshop will address various aspects of the use of animals in research and the role of animals and alternatives in research and education. The workshop will address such issues as (1) Adequacy of Computer Searches; (2) NIH, USDA, FDA Alternatives Initiative; (3) Occupational Health - Implementation, Update and Biosafety Concerns; (4) Roles of Animals and Alternatives in Education.

DATES: December 1-2, 1994

TOPIC: New Frontiers in Surgery

LOCATION

Sheraton Charleston
170 Lockwood Drive
Charleston, SC 29403
Telephone: (803) 723-3000
FAX: (803) 723-3000

SPONSOR: Medical University of South Carolina

REGISTRATION
M. Michael Swindle, D.V.M.
MUSC/Comparative Medicine
171 Ashley Avenue
Charleston, SC 29425-2211
Telephone: (803) 792-3625
FAX: (803) 792-9067

FEE: \$150.00 (Before Nov 15, 1994) \$175.00 (After Nov 15, 1994)

DESCRIPTION: The Workshop will address ethics, protocol review and technical and training aspects related to new surgical and interventional technologies. Topics to be discussed in the program include xenographic procedures, fetal intervention, transgenic technologies, and use of biomaterials in orthopedic surgery.

INQUIRIES

For further information concerning future NIH/OPRR Animal Welfare Education Workshops, contact

Mrs. Roberta Sonneborn
Office of Protection from Research Risks
National Institutes of Health
Building 31, Room 5B63
Bethesda, MD 20892
Telephone: (301) 496-7163
FAX: (301) 402-2803

NATIONAL HUMAN SUBJECT PROTECTIONS WORKSHOPS

NIH GUIDE, Volume 23, Number 26, July 15, 1994

P.T. 42; K.W. 0783005

National Institutes of Health
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

DATES: September 22-23, 1994

TOPIC: Human Subject Protections Workshop

LOCATION: Hyatt Regency Two Fountain Plaza, Buffalo, NY

SPONSORS
University at Buffalo
National Institute of Mental Health, NIH

CONTACT
Office of Research
University at Buffalo
State University of New York
314 Crofts Hall
Buffalo, NY 14260-1234
Telephone: (716) 645-3869

DESCRIPTION: Human Institutional Review Boards (IRBs) are charged with the responsibility to protect human subjects undergoing research while at the same time permitting the advancement of the biomedical sciences in alleviating human disease. This workshop will address specific complex issues confronting IRBs today including the issues involving the mentally incapacitated individual, research in AIDS, children, research in the emergency room, medical devices and multicenter FDA monitoring. Discussions of what constitutes an expedited review and the elements of an informed consent are also included. Full audience participation in all presentations is welcomed and encouraged. The faculty consists of outstanding individuals with expertise in the operation and function of IRBs including representatives of the OPRR, the FDA, and local colleagues. The workshop is intended for physicians, nurses, pharmacists, basic scientists, students, legal experts, members of IRBs and all persons with an interest in and concern for human research.

INQUIRIES

For further information regarding these workshops or future NIH/FDA National Human Subject Protections Workshops, contact:

Ms. Darlene M. Ross
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 5B63
Bethesda, MD 20892
Telephone: (301) 496-8101

NICHD TRANSGENIC MOUSE DEVELOPMENT FACILITY

NIH GUIDE, Volume 23, Number 26, July 15, 1994

RFP AVAILABLE: NICHD-CRMC-95-01

P.T. 34; K.W. 0780035

National Institute of Child Health and Human Development

The National Institute of Child Health and Human Development (NICHD) has a requirement for a facility to produce customized transgenic mice. Responsibilities of the facility will include: (1) receiving donor DNA probes, (2) analyzing DNA for microinjection, (3) microinjecting DNA constructs into fertilized one-cell mouse eggs and reimplanting into pseudopregnant recipient females, (4) testing potential founders for DNA integration, (5) producing at least two integration-positive transgenic mice, (6) maintaining the transgenic for a short period, and (7) distributing the transgenics. The Request For Proposal (RFP) will be available on or about July 11, 1994, and responses are due by September 7, 1994. All responsible sources are encouraged to submit a proposal.

INQUIRIES

All requests must cite the RFP number above and include two self-addressed mailing labels. All sources who consider themselves qualified are encouraged to submit proposals.

Mrs. Dorothy McKelvin
Office of Grants and Contracts
National Institute of Child Health and Human Development
6100 Building, Room 7A07
Bethesda, MD 20892
FAX: (301) 402-3676

ANIMAL CARE AND HOUSING SUPPORT SERVICES FOR STUDY OF SLOW, LATENT AND TEMPERATE INFECTIONS OF THE NERVOUS SYSTEM CAUSED BY CONVENTIONAL AND UNCONVENTIONAL VIRUSES

NIH GUIDE, Volume 23, Number 26, July 15, 1994

RFP AVAILABLE: NIH-NINDS-94-08

P.T. 34; K.W. 1002002, 1002045

National Institute of Neurological Disorders and Stroke

The Division of Intramural Research of the National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), is seeking a contract for animal care and housing support services for the study of slow, latent and temperate infections of the nervous system caused by conventional and unconventional viruses. Housing and care of this colony includes providing animal management, veterinary care and treatment, laboratory services, and other technical support and specified on-site facilities--as described in the Request for Proposals (RFP)--in an isolated, scrapie-free environment. The colony includes approximately 770 non-human primates, five equine, three goats, and three domestic cats in support of ongoing, long-term research studies. Offerors must have on-site veterinary care, extensive knowledge of and experience with infectious diseases, and be well versed in prescribed guidelines on the use and care of laboratory animals. This requirement represents the recompetition of a current contract with the University of Southwestern Louisiana and the incumbent is expected to reapply. It is anticipated that one award covering a performance period of five years will be made about February 1995.

INQUIRIES

This is not an RFP. An RFP will be issued on or about July 28, 1994, with proposals due by September 28, 1994. All responsible sources will be considered by the agency.

To receive a copy of the RFP, submit a written request with two self-addressed mailing labels to:

Contracting Officer
ATTN: RFP No. NIH-NINDS-94-08
Division of Extramural Activities
National Institute of Neurological Disorders and Stroke
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, MD 20892

NIH GUIDE, Volume 22, Number 26, July 15, 1994

RFA AVAILABLE: CA-94-026

P.T. 34; K.W. 0715035, 0745003, 0740018, 0755015

National Cancer Institute

Letter of Intent Receipt Date: August 25, 1994

Application Receipt Date: October 13, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites applications for cooperative agreements to support clinical trials that are directed toward examining the role of various chemopreventive agents and/or diet in the prevention of cancer. This is a follow-up to earlier RFAs that had requested grants, and then later, cooperative agreement applications in this area.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Prevention Clinical Trials Utilizing Intermediate Endpoints and Their Modulation by Chemopreventive Agents, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications from minority and women investigators are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) cooperative agreement mechanism (U01), for which substantial NIH programmatic involvement is expected. An assistance relationship will exist between NCI and the awardees to accomplish the purpose of the activity. The recipients will have primary responsibility for the development and performance of the activity. However, there will be government involvement with regard to (1) assistance securing an Investigational new Drug (IND) approval from the Food and Drug Administration (FDA), (2) monitoring of safety and toxicity, (3) coordination and assistance in obtaining the chemopreventive agent, and (4) quality assurance with regard to the clinical chemistry aspects of the study. Responsibility for planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for an application submitted in response to the present RFA may not exceed five years.

This RFA will be issued annually for two years. Future unsolicited continuation applications will compete with all other investigator-initiated (R01) research applications and be peer reviewed by a study section in the DRG. However, should the NCI determine subsequently that there is a sufficient continuing program need, NCI may reissue a new RFA and invite all funded recipients to submit competing continuation applications. In the latter case, competing continuation applications will not compete with new applications for funding.

FUNDS AVAILABLE

Approximately \$1.5 million in total costs for the first year will be committed to fund applications submitted in response to this RFA. The project period cannot exceed five years. It is anticipated that three to five awards will be funded.

RESEARCH OBJECTIVES

The major objective of this solicitation is to encourage cancer chemoprevention clinical trials that utilize biochemical and/or biological markers to identify populations at risk and/or to provide intermediate endpoints that may predict later reduction in cancer incidence rates.

These studies may be developed in phases, including a pilot phase, which could later proceed to a full-scale intervention. The main emphasis should be on small, efficient intervention studies aimed at improving future research designs of chemoprevention trials, providing further biologic understanding of the trial results, or providing better, more quantitative and more efficient endpoints for these trials. After successful completion of the pilot phase (i.e., demonstrated modulation of marker endpoints by the intervention), subsequent studies could include a definitive clinical trial monitoring the test system, a cancer incidence or mortality endpoint, and a designated agent.

Investigators may apply at this time for the pilot phase, or submit an application for both the pilot and definitive trial studies. However, if the application is for the pilot phase only, it must include a description of its relevance to a broad clinical application, including the chemopreventive agent, marker test system, and study population which could later be the subject of a full-scale, double-blind, randomized, risk reduction clinical trial. Intermediate marker trials of breast cancer chemoprevention are especially encouraged.

STUDY POPULATION

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by August 25, 1994, a letter of intent that includes a descriptive title of the proposed research, the name and address of the principal investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NCI staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to Dr. Marjorie Perloff at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The receipt date for application is October 13, 1994. The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these cooperative agreements. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248; and from the NCI Program Director listed under INQUIRIES.

The RFA label available in the PHS 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the title of the application, "Prevention Clinical Trials Utilizing Intermediate Endpoints and Their Modulation by Chemopreventive Agents," and the RFA number, CA-94-026, must be typed in block 2a of the face page of the application form.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, exact, clear, and single-sided, photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At time of submission, two additional copies of the application must also be sent to:

Ms. Toby Friedberg
Division of Extramural Activities
National Cancer Institute
Executive Plaza North, Room 636
6130 Executive Boulevard
Rockville, MD 20852 (if hand-delivered or delivery service)
Bethesda, MD 20892 (if U.S. Postal Service)

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by the NCI. Incomplete applications will be returned to the applicant without further consideration. If NCI staff find that the application is not responsive to the RFA, it will be returned without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NCI in accordance with the review criteria stated below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA. Applications judged to be competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the principal investigator/program director and the official signing for the applicant organization will be promptly notified.

Review Criteria

The following factors will be considered in evaluating the scientific merit of each response to the RFA:

1. Scientific merit of the study objective(s), design, and methodology to include considerations of toxicity, safety and quality assurance.
2. Basic and clinical scientific significance as well as originality of the proposed research.
3. Research experience and/or competence of the Principal Investigator and other key personnel to conduct the proposed studies.
4. Adequacy of time (effort) which the Principal Investigator and staff would devote to conduct the proposed studies.
5. Relevancy and appropriateness of the specific target population along with assurance as to its accessibility.

6. Identity of sources of data, tissues, fluids, etc., procedures for their collection and analysis, and assurances as to their accessibility.

7. Adequacy of plans for NCI program staff involvement with the proposed studies.

8. Adequacy of plan for inclusion of women and minorities.

The review group will critically examine the submitted budget and will recommend an appropriate budget and period of support for each meritorious application.

INQUIRIES

Written and telephone inquiries requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Marjorie Perloff, M.D.
Division of Cancer Prevention and Control
National Cancer Institute
Executive Plaza North, Suite 218
Bethesda, MD 20892-4200
Telephone: (301) 496-4664
FAX: (301) 402-0553

Direct inquiries regarding fiscal matters to:

Mr. Robert Hawkins
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Suite 243
Bethesda, MD 20892
Telephone: (301) 496-7800, Ext. 213

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399, Cancer Control. Awards will be made under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410,; 42 U.S.C. 241, and Section 412, as amended by Public Law 99-158, 42 U.S.C. 258a-1); and administered under and Federal regulations 42 CFR Part 52 and PHS grant policies 45 CFR Part 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

RESEARCH PROGRAM GRANTS IN CHEMOPREVENTION

NIH GUIDE, Volume 22, Number 26, July 15, 1994

RFA AVAILABLE: CA-94-022

P.T. 34; K.W. 0715035, 0745003, 0710030

National Cancer Institute

Letter of Intent Receipt Date: September 1, 1994

Application Receipt Date: October 20, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites cooperative agreements to support a research and development program of multiple projects directed towards chemoprevention of cancer, requiring a broadly based and multidisciplinary approach.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Research Program Grants in Chemoprevention, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications from minority and women investigators are encouraged.

MECHANISM OF SUPPORT

This RFA will use the cooperative agreement (U19) mechanism. The cooperative agreement is an assistance mechanism in which substantial NIH programmatic involvement with the recipient during performance of the planned activity is anticipated. The nature of Program Director's involvement is described in the RFA. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant/awardee.

If it is determined that there is a sufficient continuing need, the NCI will invite recipients of awards made in FY 95 under this RFA to submit competitive continuing applications.

As more fully described in the RFA, the recipients will have primary responsibility for the development and performance of the activity. However, there will be government involvement with regard to (1) assistance in securing an Investigational New Drug (IND) approval from the Food and Drug Administration (FDA), (2) coordination and assistance in obtaining the chemopreventive agent, (3) monitoring of safety and toxicity and, (4) quality assurance of the clinical chemistry aspects of the study. Awards will not be made until all arrangements for obtaining the IND and the agent are completed. Final awards will consider not only the cost of the clinical trial but also the cost of the agent and, if necessary, its formulation.

FUNDS AVAILABLE

Approximately \$4.0 million in total costs for the first year for project periods up to five years will be committed to specifically fund applications which are submitted in response to this RFA. It is anticipated that four to six awards will be made. This number of awards is dependent on the receipt of a sufficient number of applications of high scientific merit. The earliest feasible start date for the initial awards will be July 1995. Although this program is provided for in the financial plans of the NCI, awards made pursuant to this RFA will be contingent upon the continued availability of funds for this purpose.

RESEARCH OBJECTIVES

The Chemoprevention Branch invites research project cooperative agreement applications (U19) in chemoprevention to encourage and facilitate multidisciplinary collaborations through the coordinated submission of related research projects that share a common research theme in chemoprevention.

To be eligible for awards, the application must include a minimum of three scientifically meritorious projects, one of which must involve a clinical trial. The theme might involve a particular agent or class of agents (i.e., anti-initiators or antipromoters: retinoids, non-steroidal anti-inflammatory agents), populations (general, at risk, subjects with precancer or cancer patients free of disease), sites (breast, prostate, lung, colon), or surrogate markers. Relevant preclinical and clinical ancillary projects might include in vitro and in vivo (animal) efficacy studies, pharmacokinetic and pharmacological evaluations, biomarker studies, and nested case control evaluations. The application should include a sufficient number of scientifically meritorious projects to promote an effective collaborative effort among the participating investigators.

This particular type of research project cooperative agreement (U19) builds on the leadership of a key principal investigator and the interaction of the participating investigators in order to integrate the individual projects in a way that accelerates the acquisition of knowledge beyond that expected from the same projects conducted separately, without combined leadership or a common theme. Individual investigators may apply their specialized research capabilities to basic, developmental, and clinical aspects, as they relate to the focused central theme of the overall project. This grant mechanism also offers a special way to achieve an economy of effort through the sharing of personnel, facilities, equipment, data, ideas and concepts.

The principal investigator of the research program cooperative agreement must be an established scientist with a strong record of accomplishment, who is substantially committed to, and capable of, exercising the responsibility for the scientific leadership, integration and administration of a major effort in cancer prevention. The component projects should be directed by investigators who are experienced in the conduct of independent research and whose backgrounds and interests relate sufficiently to one another in order to allow for integrated group pursuits.

SPECIAL REQUIREMENTS

This RFA represents a single competition, with a specified deadline, October 20, 1994, for receipt of applications. It is expected that each application will describe plans for a mixture of basic, developmental, and clinical research from an investigator wanting to focus on a particular study in cancer chemoprevention. Each application should have a general focus on study outcomes, and on the application of basic research and development to human subjects and populations.

All PHS and NIH grant policies will apply to applications received in response to this announcement.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by September 1, 1994, a letter of intent that includes a descriptive title of the proposed research, the name and address of the principal investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NCI

staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to Dr. Marjorie Perloff at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these cooperative agreements. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248; and from the NCI Program Director listed under INQUIRIES.

The RFA label available in the application form PHS 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title, "Research Project Grants in Chemoprevention" and the RFA number, CA-94-022, must be typed in block 2a of the face page of the application form.

Submit a signed, typewritten original of the application, including the Checklist, and three signed clear and single-sided photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At time of submission, two additional copies of the application must also be sent to:

Ms. Toby Friedberg
Division of Extramural Activities
National Cancer Institute
Executive Plaza North, Room 636A
6130 Executive Boulevard
Rockville, MD 20852 (if hand-delivered or delivery service)
Bethesda, MD 20892 (if U.S. Postal Service)

REVIEW CONSIDERATIONS

Upon receipt, applications will be administratively reviewed (initially) by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to the RFA is an NCI program staff function. Applications will be judged to determine if they meet the goals and objectives of the program as described in the RFA.

Applications that are judged non-responsive will be returned. Questions concerning the relevance of proposed research to the RFA may be directed to the NCI Program Director.

If the number of applications is large compared to the number of awards to be made, the NCI may conduct a preliminary scientific peer review to identify those which are clearly not competitive for awards.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Marjorie Perloff, M.D.
Division of Cancer Prevention and Control
National Cancer Institute
Executive Plaza North, Suite 218
Bethesda, MD 20892-4200
Telephone: (301) 496-4664
FAX: (301) 402-0553

Direct inquiries regarding fiscal matters to:

Mr. Robert Hawkins
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Suite 243
Bethesda, MD 20892
Telephone: (301) 496-7800 Ext. 213

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.399, Cancer Control. Awards will be made under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410,; 42 U.S.C. 241, and Section 412, as amended by Public Law 99-158, 42 U.S.C. 258a-1); and administered under Federal regulations 42 CFR Part 52 and PHS grant policies 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

BEHAVIORAL THERAPIES DEVELOPMENT PROGRAM

NIH GUIDE, Volume 22, Number 26, July 15, 1994

PA NUMBER: PA-94-078

P.T. 34; K.W. 0404009, 0404000, 0415001, 0745007, 0745060

National Institute on Drug Abuse

PURPOSE

The purpose of this program announcement (PA) is to firmly establish the ongoing commitment of the NIDA to a major program of research on behavioral therapies for drug abuse and dependence. The term "behavioral therapy" is used here in a broad sense and includes various forms of psychotherapy, behavior therapy, cognitive therapy, skills training, counseling, and other rehabilitative therapies. Behavioral therapy research has been conceptualized, for the purposes of this initiative, to consist of three stages: (1) Stage I research (including the development, refinement, and pilot efficacy testing of behavioral interventions); (2) Stage II research (efficacy testing and replication of promising piloted behavioral therapies); and (3) Stage III research (studies to test the transferability to the community of behavioral therapies proven efficacious in Stage II studies).

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Behavioral Therapies Development Program, is related to the priority area of alcohol and other drugs. Potential applicants may obtain a copy of "Healthy People 2000" Full Report: Stock No. 017-001-00474-0 or Summary report: Stock No. 017-001-00473-1 through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organization, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) Awards (R29).

MECHANISM OF SUPPORT

Support mechanisms include: research project grants (R01), small grants (R03), cooperative clinical research grants (R10) and FIRST Awards (R29). Investigators may also respond to this program announcement under the Interactive Research Project Grant (IRPG) Program. If an investigator wishes to respond under an IRPG, additional requirements must be met as described in PA-93-078. Research grants are awarded to institutions on behalf of Principal Investigators who have designed and will direct a specific project or set of projects. In fiscal year 1995, it is estimated that NIDA will have approximately \$10 million to support approximately 30 new grants under this announcement.

RESEARCH OBJECTIVES

Background and Rationale. Behavioral therapies are frequently the only treatments available to drug dependent individuals. Even where medications are available, behavioral therapies are an integral component of treatment. Recognizing the importance of this area, the NIDA has launched a Behavioral Therapies Development Program. It is intended to: (1) complement and dramatically expand work underway within the Clinical and Experimental Therapeutics Research Branch, Division of Clinical Research, NIDA; and (2) parallel NIDA's Medications Development Program. It is NIDA's intention to support scientifically sound and clinically relevant behavioral therapy research that will potentially have a meaningful impact on the efficacy of drug abuse/dependence treatment. Due to the growing AIDS problem in this country, special consideration will be given to grants that address AIDS-related issues in their therapies and include measures of the effect of the therapies on AIDS risk behaviors. Through the Behavioral Therapies Development Program, support may be sought to identify, evaluate, and standardize behavioral therapies for the treatment of drug abuse and dependence. Ultimately, therapies found to be efficacious through rigorous testing will be disseminated to clinicians. Although substantial work has already been done, this initiative will target for funding, in a systematic way, essential research on behavioral therapies for drug abuse and dependence. This will include, in particular, critical areas of research that have been overlooked in the past.

Recent results from research studies indicate great promise for the efficacy of behavioral therapies for drug dependence. While considerable progress has been made, engagement and retention in treatment and relapse following treatment remain concerns. NIDA has undertaken the Behavioral Therapies Development Program with the goal of addressing these concerns and substantially improving the efficacy of behavioral treatments for drug abuse. The NIDA's Behavioral Therapies Development Program delineates three stages of behavioral therapy research. Stage I, the earliest stage of behavioral therapy research, therapy development, is viewed as a process involving identifying promising clinical and research findings relevant to drug abuse treatment, generating and formulating new behavioral therapies, operationally defining the therapies in manuals, and pilot testing and refining the therapies.

Stage II research consists of small-scale efficacy testing of promising therapies identified in Stage I, as well as studies examining the efficacy of components of therapies. Most of the behavioral treatment research that NIDA has supported in the past has been of this type. Stage II also involves the replication, at other sites, of efficacy studies with positive results.

Stage III entails the testing of the transferability to the community of therapies that have been shown to be efficacious in more than one controlled Stage II clinical trial. That is, Stage III, as defined in this program announcement, involves the determination of the usefulness of a therapy within community-based treatment programs. In order to meet

the goals of Stage III research, investigators may wish to propose the development of training materials for the community drug abuse treatment provider.

It is NIDA's objective to ensure sufficient emphasis and support for all stages of behavioral therapy research. Through the Behavioral Therapies Development Program, NIDA will greatly increase its support of the early stages of behavioral therapy development, small-scale controlled clinical trials of fully-developed therapies (including replications), and studies in community-based treatment programs of the most promising therapies identified in the Stage II clinical trials. This PA is intended to introduce this initiative by encouraging research grant applications in any one of the three stages of behavioral therapy research.

Specific Areas of Interest

Stage I Research. Investigators are encouraged to submit applications to develop and pilot test new or to modify and pilot test existing individual, group or family behavioral therapies that (1) appear promising for the treatment of drug dependent and abusing individuals and (2) have a theoretical basis and/or logical rationale. For drug abusers/addicts at high risk for AIDS, investigators are encouraged to include AIDS risk reduction interventions as an integral component of the therapy. Wherever appropriate, applicants are strongly encouraged to address how they will incorporate AIDS risk reduction strategies into the therapies they are proposing to develop. Of particular interest for development are: (1) discrete therapy modules, such as HIV risk reduction modules or modules to engage ambivalent drug dependent individuals in treatment, that can be implemented in conjunction with other therapeutic services; (2) therapies to treat populations with co-occurring drug abuse and mental problems; (3) therapies that address the unique needs and perspectives of women, minorities, adolescents, families, or specific cultural groups; (4) group therapies; and (5) therapies for HIV-positive drug abusers/addicts.

Applicants proposing to develop a therapy are encouraged to explicitly describe the theoretical basis for the proposed therapy, and the population for whom it is intended. Although, of course, a manual for a therapy will not exist prior to an application to develop such a manual, applicants are encouraged to describe in as much detail as possible the nature of the therapy to be developed.

Where appropriate, applicants may seek support under this program announcement to develop theoretically-based and psychometrically-sound client assessment scales tailored to assess the specific effects of the proposed therapy. If one theorizes, for example, that certain heroin addicts either began or maintained heroin use due to interpersonal conflicts, and that the resolution of these conflicts will decrease drug use, a measure of interpersonal conflicts may be required to ascertain the impact of the therapy under development.

Applicants are encouraged to address the issue of therapy process measurement. Where appropriate, applicants may propose to develop measures of therapist competence and adherence, process measures, and instruments measuring the integrity and fidelity of the therapy.

In the development of a new therapy for drug dependence, a broad range of issues relevant to efficacy and safety are raised. Pilot efficacy testing of newly developed/modified therapies is an integral part of any therapy development process. Therefore, applicants are encouraged to describe, in detail, the nature of any pilot testing intended.

Wherever appropriate, applicants are encouraged to collect pilot data on the impact of the therapy on AIDS risk behavior, including data on the route of drug administration, and sexual behavior that may place individuals at risk for AIDS. **Stage II Research.** According to the model described in this program announcement, Stage II research establishes the efficacy of behavioral therapies or therapy components shown to be promising in Stage I. Therefore, it is strongly suggested that Stage I pilot data showing that a behavioral therapy is promising (in terms of a reduction in drug use, dropout rate, or psychiatric symptoms) be provided when proposing a Stage II controlled clinical trial. In Stage II research, control and comparison conditions are operationally defined, standardized, and manualized. However, early in Stage II, it may be appropriate to compare a therapy with "treatment as usual." Of course, control/comparison conditions are determined by clearly delineated research questions. It is appropriate, but not required, that investigators design studies to answer not only if their therapy works, but why it works. Where investigators are studying populations that are at risk for HIV, they are encouraged to explicitly address AIDS-related issues in their applications.

Controlled clinical trials that examine the relative efficacy of individual, group, or family behavioral therapies and attempt to determine which therapies are best for which individuals, and under what conditions, are considered Stage II research. Where effective pharmacotherapies are available, research projects that attempt to maximize the efficacy of that pharmacotherapy through integration with behavioral therapy, or vice versa, are encouraged.

Knowing the effective components of treatment can greatly aid in improving the quality of treatment. Theoretically based research that attempts to determine the effective components or combination of components in drug dependence psychotherapies, behavior therapies, or counseling strategies is encouraged.

Where positive Stage II findings exist, replications are strongly encouraged. Applications that propose to generalize the efficacy of a promising therapy in another population are also encouraged. Where the investigator believes that significant modification of the therapy is needed before it can be tested in another population, investigators are referred to the section of this PA entitled, "Stage I Research."

Investigators proposing a Stage II controlled clinical trial are encouraged to address pertinent methodological/design issues in their applications, such as attrition, selection bias, therapist/counselor training, assessment and control for patient psychiatric diagnosis and problem severity level, the use of manuals to guide the therapy, measurement of the treatment process, adequate follow-up assessments, and potential replication of the research proposed. It is recognized that for many research questions asked in the field of psychotherapy, behavior therapy, and counseling, no perfect research design may exist. Where there is more than one way to answer a proposed research question, investigators are urged to state their theoretical, ethical, and practical reasons for choosing one control group or one research design over another.

Stage III Research. Where a behavioral therapy has been shown to be efficacious in a clinical trial, and where replication by a different investigator has borne out the contention that the therapy is, indeed, efficacious,

investigators may propose to carry out a study to address the therapy's transferability to a community setting. A therapy that has been shown to be efficacious in a Stage II clinical trial and a replication is a possible candidate for a Stage III study. An investigator may propose to do a Stage III study on a therapy that was determined to be efficacious in Stage II by themselves or other investigators.

Stage III may include packaging a therapy for use by a community drug abuse treatment provider and developing training manuals and other training materials. The investigator might then pilot the therapy in the community clinic, refine the therapy package, and ultimately test the usefulness of the packaged therapy in the community setting.

Applicants are strongly encouraged to develop applications that are focused on one stage. That is, investigators may choose to focus on either Stage I, Stage II or Stage III research. However, where necessary, investigators may develop applications to include a research component consistent with the another stage (e.g., a Stage II research application may include a small Stage I component).

If a subject is identified as being at risk for HIV acquisition and/or transmission, HIV testing and counseling must be offered to the subject in accordance with current guidelines. Wherever appropriate, investigators are encouraged to collect data on the effect of their behavioral therapy on AIDS risk behaviors and the effect of their therapy on the acquisition/transmission of associated infectious disease, including HIV.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 28, 1994 (FR 59 11146-11151), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the program staff or contact person listed below. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit. The receipt dates for applications for AIDS-related research are found in the PHS 398 instructions. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 240, Bethesda, MD 20892, telephone (301) 594-7248. The title and number of the program announcement must be typed in Section 2a on the face page of the application.

FIRST applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit in accordance with the standard peer review procedures. Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council. Small grant applications (R03) assigned to NIDA do not receive a second-level review.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that Institute/Center/Division. At NIDA, special consideration will be given to applications that directly deal with AIDS-related issues. The following will be considered when making funding decisions:

- o Scientific and technical merit of the proposed project as determined by peer review
- o Availability of funds
- o Institute/Center/Division program needs and balance

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applications is welcome.

Direct inquiries regarding programmatic issues to:

Dr. Lisa Onken
Clinical and Experimental Therapeutics Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 10A-30
Rockville, MD 20857
Telephone: (301) 443-0107
INTERNET: lonken@aoada.ssw.dhhs.gov

Direct inquiries regarding fiscal matters to:

Dr. Gary Fleming, Chief
Grants Management Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 8A-54
Rockville, MD 20857
Telephone: (301) 443-6710

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.279. Awards are made under authorization of the Public Health Service Act (42 USC 241 and 290cc) and administered under PHS grants policies and Federal Regulations at Title 42 CFR Part 52, "Grants for Research Projects," Title 45 CFR part 74 & 92, "Administration of Grants," and 45 CFR Part 46, "Protection of Human Subjects." Title 42 CFR Part 2 "Confidentiality of Alcohol and Drug Abuse Patient Records" may also be applicable to these awards. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Sections of the Code of Federal Regulations are available in booklet form from the U.S. Government Printing Office. Awards must be administered in accordance with the PHS Grants Policy Statement, (Rev., 4/94), which may be available from the institutional office of sponsored research.

DNA DAMAGE, GENOMIC INSTABILITY AND BREAST CANCER

NIH GUIDE, Volume 22, Number 26, July 15, 1994

PA NUMBER: PA-94-079

P.T. 34; K.W. 0715036, 0755030, 0760053, 1002019

National Cancer Institute

PURPOSE

The Division of Cancer Etiology of the National Cancer Institute (NCI) invites grant applications from interested investigators through a Program Announcement (PA) to establish whether or not there is greater genomic instability associated with individuals in families with hereditary breast cancer than in individuals that do not have a family history of cancer. This initiative is in response to Congressional language that NCI emphasize studies on the etiology of female breast cancer as one of its top priorities.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, DNA Damage, Genomic Instability and Breast Cancer, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0; Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal government. Applications from minority and women investigators are encouraged.

MECHANISM OF SUPPORT

This PA will be supported through the National Institutes of Health (NIH) traditional research project grant (R01). The applicant will have the sole responsibility for planning, directing and executing the proposed research. Because the nature and scope of the research proposed in response to this PA may vary, it is anticipated that the size of an award will vary also.

RESEARCH OBJECTIVES

Background

The generally accepted mutation model of cancer requires a small number of select mutations, all in a single cell, for the development of cancer. An increase in mutation rate would significantly decrease the time of onset. Such a mutation rate increase could result from a mutation in any of the multiple genes that affect genomic stability. Because there are multiple sites on each gene for impairing or inactivating normal function, there is a high probability for the formation of genetically unstable clones or mosaics during normal human development (for a pertinent review see: K.C. Cheng and L.A. Loeb, *Adv. Cancer Res.* 60:121-156, 1993). The association of karyotypic abnormalities with cancer cells and with normal cells from individuals with various syndromes predisposing to cancer suggests that karyotypic instability as a phenotype can be transmitted through the germline and underlies a substantial fraction of the changes required for cancer expression. It is conservatively estimated that one hundred genes are involved in maintaining genomic fidelity. A functional decline in any one of them would be expected to increase the mutation rate. This suggests that genomic instability phenotypes other than karyotypic instability also may exist.

The possibility that genomic instability, originating from the germline and/or somatically acquired, is a significant element in the initiation or progression of a cell to cancer is important to establish. This possibility would provide for additional segregation ratios, less than the dominant ratio of 0.5, which are frequently suggested by investigations of cancer families, and it would strongly suggest that hereditary cancer is associated with a significantly greater fraction of the overall incidence than is presently believed.

Objectives

The goal of this PA is to encourage research on human breast cancer using molecular, biochemical and cytogenetic techniques to determine whether or not a genomic instability in non-tumorigenic cells is associated with familial breast cancer family members both with and without cancer. Normal individuals with no family history of cancer could serve as controls. Suitable cells for this approach might include circulating lymphocytes, normal breast epithelial cells, normal fibroblasts or other appropriate cell types. The term "genomic instability" is taken broadly to mean a significant difference, presumably a decrease from an established normal base line, in any of various parameters expected to decrease the integrity of the cellular genome or its expression. Study of parameters toward this end could include, but need not be limited to: (1) Determination of the relative capacity of suitable cells from members of breast cancer families to repair DNA damaged by either radiation or chemical carcinogens. Analogous cells from individuals who do not have a family history of cancer would serve as normal controls. (2) Determination of the relative abilities of suitable cells from breast cancer family members to deactivate genotoxic chemicals compared with those from normal (as defined above) controls. (3) Determination of the relative capacity of suitable cells from breast cancer family members to repair chromosome or chromatid damage from radiation or chemicals compared to those from normal (as defined above) controls. (4) Comparison of the sensitivity of appropriate cells from breast cancer family members and those from normal (as defined above) controls to the initial damage of DNA by radiation or chemicals. (5) Comparison of the relative capacities of suitable cells from breast cancer family members and those from normal (as defined above) controls to maintain the primary sequence of DNA, i.e., replication fidelity, proof reading capacity, prevention of DNA damage and recombination fidelity.

Because these investigations can involve several disciplines, both interdisciplinary studies and more focused investigations are appropriate.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director or principle investigator could be included with the application.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research," which was reprinted in the Federal Register of March 28, 1994 (59 FR 14508-14513) to correct typesetting errors in the earlier publication, and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the staff listed below. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications must be submitted on form PHS 398 (rev. 9/91), available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301-594-7248. The format and instructions applicable to regular research grant applications must be followed in preparing an application in response to this PA.

The number and title of the PA must be typed on line 2a of the face page of the application and the YES box must be checked. A signed, typewritten original grant application, including the checklist, and five signed, exact photocopies, must be mailed, in one package, to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the Division of Research Grants for completeness. Incomplete applications will be returned to the applicant without further consideration. Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures.

AWARD CRITERIA

Scientific merit, contribution to overall programmatic balance, and availability of funds will be major criteria for making award decisions.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Raymond Gantt, Ph.D.
Division of Cancer Etiology
National Cancer Institute
Executive Plaza North, Suite 530
Bethesda, MD 20892
Telephone: (301) 496-9326
FAX: (301) 496-1224

Inquiries regarding fiscal matters may be directed to:

Mr. Earl Bowman
Grants Administration Branch
National Cancer Institute
6120 Executive Boulevard, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800 ext. 217
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.393, Cancer Cause and Prevention Research. Awards are made under authorization of Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grant policies and Federal regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

GENETIC AND PHENOTYPIC MARKERS FOR IONIZING RADIATION-INDUCED BREAST CANCER IN RODENT AND HUMAN CELLS

NIH GUIDE, Volume 22, Number 26, July 15, 1994

PA NUMBER: PA-94-080

P.T. 34; K.W. 0715036, 0755030, 0760053, 1002019, 0765014

National Cancer Institute

PURPOSE

The Division of Cancer Etiology of the National Cancer Institute (NCI) invites grant applications from interested investigators through a Program Announcement (PA) to study changes of gene expression that are induced by exposure of pluripotent, or partially transformed, rodent and human mammary epithelial cells to ionizing radiations; and to define the role of such gene sequences in the progression to radiogenic breast cancer in rodent models. This initiative is in response to Congressional language that NCI emphasize studies on the etiology of female breast cancer as one of its top priorities.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Genetic and Phenotypic Markers for Ionizing Radiation-Induced Breast Cancer in Rodent and Human Cells, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0; Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit institutions, public and private, such as universities, colleges, hospitals, laboratories, units of state or local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This PA is a one-time solicitation and will be supported through the National Institutes of Health (NIH) traditional research project grant (R01). The applicant will have the sole responsibility for planning, directing and executing the proposed research. Because the nature and scope of the research proposed in response to this PA may vary, it is anticipated that the size of an award will vary also.

RESEARCH OBJECTIVES

Background

Young adult women and adolescent females under 20 years of age may be unusually susceptible to ionizing radiation-induced breast cancer (e.g., atomic bomb survivors, young female Hodgkin's lymphoma patients treated by radiotherapy). There also is evidence that young female rodents show increased sensitivity to both chemical-induced and radiation-induced mammary cancer. Several lines of evidence, based partly on the growth characteristics of cultured human breast carcinoma cells and more strongly on experimental work on the induction of mammary tumors in rodents, suggest that populations of precursor or pluripotent stem-like cells that are prevalent during the formation and differentiation of the mammalian female breast tissue are the main targets for ionizing-radiation-induced genetic damage that eventually may give rise to cancer.

Objectives

This PA encourages research applications to study the etiologic and mechanistic basis for the apparent susceptibility of pluripotent cells implanted into the developing breast tissue of rodents to undergo malignant transformation by ionizing radiation. It will focus on the characterization and analyses of the genes and gene products that may be differentially expressed during the progression of these precursor, or partially transformed, rodent mammary epithelial cells into malignant breast cancers. Particular emphasis will be given to defining the possible etiologic roles of such gene sequences in the early stages of progression prior to malignancy (e.g., mutations that result in increased dysplasia and loss of differentiation capabilities in vivo; acquisition of growth factor and hormonal independence for cellular proliferation in vitro). Where feasible, comparative in vitro or in vitro/in vivo studies of the effects of ionizing radiation on non-malignant human mammary epithelial cells will be encouraged. Because of the scope of the studies, involving both whole animals and molecular and cellular endpoints, multidisciplinary applications are encouraged.

The PA includes, but is not limited to:

- o A determination of the susceptibility and involvement of precursor-like mammary epithelial cells in radiation-induced breast cancer in the developing mammary tissue of young female rodents;
- o The isolation and subsequent genetic and biochemical analyses of gene sequences and gene products that are differentially over- or under-expressed during progression to radiogenic breast cancer in rodent and, if feasible, in human breast epithelial cells;
- o The assessment, following radiation exposure, of differentially expressed genes, proteins or mutations in breast epithelial precursor cells to serve as biomarkers of preneoplastic lesions for radiation-induced breast carcinomas in rodents and humans.

STUDY POPULATIONS

Special instructions to applicants regarding implementation of NIH policies concerning inclusion of females and minorities in research involving human subjects are not applicable to this PA. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded from the usual NIH policies on gender and minority representation in human subjects. However, every effort should be made to include tissues from racial/ethnic minority women when it is important to apply the results of the study broadly to human populations, and this issue should be addressed by the applicants.

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91), available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone, (301) 594-7248. The format and instructions applicable to regular research grant applications must be followed in preparing a grant in response to this PA.

The number and title of the PA must be typed on line 2a of the face page of the application and YES must be checked. A signed, typewritten original grant application, including the checklist, and five signed, exact photocopies, must be mailed, in one package, to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the Division of Research Grants for completeness. Incomplete applications will be returned to the applicant without further consideration. Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures.

Review Criteria

1. The scientific and technical significance of the proposed research;
2. The adequacy of the methodology to carry out the research;
3. The qualifications and experience of the Principal Investigator and staff;
4. Reasonable availability of resources;
5. Reasonableness of the proposed budget and duration;
6. Other factors: e.g., human subjects, animal welfare, and biohazards

AWARD CRITERIA

Scientific merit and contribution to overall programmatic balance and the availability of funds will be major criteria for making award decisions.

INQUIRIES

Written and telephone inquiries concerning the scientific objectives and scope of this PA are encouraged and may be directed to:

Richard A. Pelroy, Ph.D.
Division of Cancer Etiology
National Cancer Institute
Executive Plaza North, Room 530
6130 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-9326
FAX: (301) 496-1224

Direct inquiries regarding administrative and fiscal matters to:

Ms. Lauren Neumann
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 242
6120 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 264
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.393, Cancer Cause and Prevention Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74.

MINORITY HIGH SCHOOL STUDENT RESEARCH APPRENTICE PROGRAM

NIH GUIDE, Volume 22, Number 26, July 15, 1994

PA NUMBER: PAR-94-081

P.T. 44; K.W. 0720005, 0502000

National Center for Research Resources

Application Receipt Date: October 18, 1994

PURPOSE

The National Center for Research Resources (NCRR), National Institutes of Health (NIH), plans to continue the Minority High School Student Research Apprentice Program (MHSSRAP) in 1995 during the phase in of the new "NCRR Minority Initiative: K-12 Teachers and High School Students." The purpose of the MHSSRAP program is to provide minority high school students with a meaningful experience in various aspects of health-related research in order to stimulate their interest in careers in science. The program also includes in-service elementary, middle, junior, and senior high school teachers, and potential K-12 science teachers in pre-service education programs. Eligible teachers will still be those who are members of a minority group or who teach a significant number of minority students. Teachers may participate in the program for a second year. The hands-on summer research project must be structured to update the teachers' knowledge and skills in modern research tools and techniques as well as to strengthen their teaching skills. The experience should provide teachers the opportunity to bring back to the classroom a sense of the excitement of research that would stimulate students to pursue scientific careers. A longer range goal is to establish year round linkages between pre-service and in-service science teachers, elementary and secondary school students, and biomedical researchers.

Awards are contingent on the availability of appropriated funds. Thus, allocations may be reduced below the amount requested in the application. Upon recommendation of the National Advisory Research Resources Council, the NCRR will give preference in making awards to those institutions that can support a summer program having a "critical mass" of at least five or six students.

ELIGIBILITY REQUIREMENTS

Eligible organizations or organizational components are those domestic, non-profit organizations that (1) at the time of application, received at least three NIH research grants in the research grants base (defined below) totaling \$200,000 in FY 1994; (2) have this minimum threshold of active NIH research grant support, excluding no cost extensions, at time of award; and (3) did not receive a FY 1994 award under the NCRR Minority Initiative K-12 Teachers and High School Students. (For purposes of this program, the "research grants base" is defined as those grants awarded with the following activity codes: K01, K02, K04, K05, K06, K08, K11, K12, K14, K15, K16, K20, K21, P01, P40, P41, P42, P50, P60, R01, R03, R10, R21, R24, R29, R35, R37, R55, S06, S14, U01, U10, U24, U42, and U54.) Recipients of an active Minority Biomedical Research Support (MBRS) Grant are also eligible.

Under-represented minority students and teachers are defined as individuals who identify themselves as Black, Hispanic, Native American, Pacific Islander, or any particular ethnic or racial group that has been determined by the grantee institution to be under-represented in biomedical or behavioral research.

Participants eligible for support must be U.S. citizens or have a permanent visa. Eligible students are those who are enrolled in high school during the 1994-1995 academic year. (Students who will graduate from high school in 1995 are eligible, as is a student who participated in a previous year provided he/she is still enrolled at the high school level.)

MECHANISM OF SUPPORT

The mechanism of support for this program will be the NIH supplement (S03).

Awards will be for one year beginning March 1, 1995, contingent upon availability of appropriated funds. Support will be provided at a level of \$2,000 for each student apprentice, \$3,000 for each pre-service teacher, and \$5,000 for each in-service science teacher. Applications may request both students and teachers or students only. No indirect costs will be paid. Direct support must be as salary; stipends are not allowed. Funds allocated may also be utilized for supplies, extending the research experience, or if adequate funds exist, for the addition of a student apprentice. However, funds from these grants may only be used for the costs of the apprentice program. The Program Director is responsible for the recruitment and selection of the apprentices and science teachers and assignment of each to an appropriate investigator. Because the nature and scope of the proposed activities submitted in response to this program announcement may vary, it is anticipated that the size of an award will vary also.

Students. Recruitment and selection of students must emphasize factors including the student's motivation, ability, scholastic aptitude, and accomplishments. In addition, consideration must be given to science teachers' recommendations and, whenever possible, the degree of parental commitment. Assignments must be made to investigators involved in health-related research who are committed to increasing the high school student's understanding of research and the technical skills needed.

Teachers. Recruitment and selection criteria for in-service teachers must include: experience and teaching responsibilities, level of interest in participating in a research program, expected impact on their teaching programs, ability to stimulate minority students to pursue scientific careers, and future plans for continued interaction with the research institution. Potential teachers should be enrolled in pre-service programs and have an expressed interest in teaching life sciences at the K-12 level.

APPLICATION PROCEDURES

The application consists of (a) a letter stating the justification for the number of student and teacher positions requested (preference will be given to those institutions with a demonstrated commitment and a documented history of encouraging students to pursue scientific careers) and (b) the original and one signed and completed copy of the face page, page 4 "Detailed Budget for First 12-Month Budget Period Direct Costs Only," and checklist pages of the grant application form PHS 398 (rev. 9/91). The required pages of the PHS 398 application form must be completed according to instructions provided in the PHS 398 (rev. 9/91) kit except for the following:

Face Page

Item 1 - Leave blank.

Items 2a and 2b - Check the box marked "YES" and type in the number and title of this Program Announcement.

Items 4 and 5 - Not applicable; do not complete.

Item 6, Dates of entire proposed project period - Enter 03-01-95 through 02-29-96.

Item 7 and 8 - Insert the total dollar amount of the request, which is the sum, from application page 4, of the number of student positions requested times \$2,000 per student; the number of pre-service teachers requested times \$3,000; and the number of in-service teachers times \$5,000. No indirect costs will be provided; thus the direct and total costs will be the same.

Item 14 - Enter the appropriate organizational code (see descriptive information provided on page 15 of the PHS-398 form). Note that no credit will be given for the S03 application.

Page 4, "Detailed Budget for First 12-Month Budget Period Direct Costs Only" - Using ONLY the Other Expenses category, enter on separate lines the number of students requested at \$2,000 per student; the number of pre-service teachers requested at \$3,000 per teacher; and the number of in-service science teachers requested at \$5,000 per teacher.

Enter the sum of the amounts requested for each under the "TOTALS" column for the Other Expenses category and under "Total Direct Costs for First 12-Month Budget Period" at the bottom of the page.

The original and one copy of the student and teacher report(s), signed by the Program Director, must be submitted with the renewal application by October 15, 1994 so that the data contained in these reports can be used by NCRR to decide about policies and future funding for the MHSSRAP.

These reports should also be submitted at the same time even if renewal support is not requested. All reports, including the Financial Status Report, must be submitted to the NIH by the grantee institution no later than May 31, 1995, unless an extension of the budget period end date has been authorized in writing.

Applications must be received by October 18, 1994 by:

Office of Grants and Contracts Management
National Center for Research Resources
Westwood Building, Room 849
Bethesda, MD 20892**

DO NOT MAIL THE APPLICATION TO THE DIVISION OF RESEARCH GRANTS, NIH.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Marjorie A. Tingle, Ph.D.
Biomedical Research Support Program
National Center for Research Resources
Westwood Building, Room 10A-11
Bethesda, MD 20982
Telephone: (301) 594-7947

Direct inquiries regarding fiscal matters to:

Ms. Mary V. Niemiec
Office of Grants and Contracts Management
National Center for Research Resources
Westwood Building, Room 849
Bethesda, MD 20982
Telephone: (301) 594-7955

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.337, Biomedical Research Support. Grants will be awarded under the authority of the Public Health Service Act, Section 301 (a)(3); Public Law 78-410 (42 USC 241) as amended, and administered under PHS grants policies and Federal Regulations 45 CFR 74 and the Guidelines for Minority High School Student Research Apprentice Program. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NCRR MINORITY INITIATIVE: K-12 TEACHERS AND HIGH SCHOOL STUDENTS

NIH GUIDE, Volume 22, Number 26, July 15, 1994

PA NUMBER: PAR-94-082

P.T. 44; K.W. 0720005, 0502000

National Center for Research Resources

Application Receipt Date: September 12, 1994

PURPOSE

As part of its continuing commitment to strengthen the quality of precollege health science education, the National Center for Research Resources (NCRR) encourages the submission of applications for a program aimed at increasing the pool of underrepresented minority high school students who are interested in pursuing and academically prepared to pursue careers in biomedical/behavioral research and the health professions. The program will include both K-12 inservice and preservice teachers and minority high school students. This program, the "NCRR Minority Initiative: K-12 Teachers and High School Students," was first announced in FY 1994 to replace the S03 "Minority High School Student Research Apprentice Program" (MHSSRAP), which is being phased down. This program announcement represents the second phase of this transition. During this continued transition, applicants for this program may also submit an application for October 15, 1994 deadline for the FY 1995 MHSSRAP. However, it is not expected that the MHSSRAP will be available for FY 1996.

The main component of this program is to provide structured summer science research experiences under the direction of active biomedical/behavioral researchers for both teachers and minority high school students. The individualized research experiences and other activities are intended to: (1) allow teachers to keep pace with the explosive growth of scientific knowledge in health-related areas, enable them to develop new discovery-oriented educational strategies,

and transfer this new knowledge to their students; and (2) provide students with a personalized, hands-on exposure to health-related research that stimulates their research interest and encourages decisions towards careers in the health sciences. A long-range goal of the program is to establish and/or strengthen partnerships between biomedical research institutions and K-12 schools by developing mentoring ties among teachers, minority students, and biomedical/behavioral researchers that will result in creating more pathways for minority students to establish careers in the health sciences.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. High schools may not apply.

Underrepresented minorities are defined as individuals belonging to a particular ethnic or racial group that has been determined by the grantee institution to be underrepresented in biomedical or behavioral research. Individuals who have been found to be underrepresented in biomedical or behavioral research nationally include Black Americans, Hispanic Americans, Native Americans, and Pacific Islanders.

Students are defined as those who are enrolled in high school during the current academic year, or who have just graduated from high school. Participants must be U.S. citizens or have a permanent visa.

Inservice teachers include elementary, middle, junior, and senior high school science teachers. In order to maximize the program's impact on minority students, teachers must be members of a minority group or teach a significant number of minority students. Preservice teachers are those teachers in training and enrolled in preservice education programs and who have expressed an interest in teaching life sciences at the K-12 level with a focus on minority students.

MECHANISM OF SUPPORT

Awards under this Program Announcement will use the education project (R25) grant mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant.

The total project period for applications submitted in response to this Program Announcement may not exceed three years. Because of the wide range in the size and type of institutions that may apply, it is anticipated that the sizes of the awards may also vary. The anticipated award date is April 1, 1995.

Applications must request support for both students and teachers, with a minimum of eight students per year unless exceptional justification is provided.

Indirect costs, other than those awarded to State or local government agencies, will be reimbursed at eight percent of total allowable direct costs. State and local government agencies will receive reimbursement at their full indirect cost rate.

Allowable costs

Funds for personnel costs may only be requested for eligible students and teachers and must be paid as salaries and wages; stipends are not allowable costs under this program. While grantee institutions must establish the rate of compensation to be paid to teachers, it is expected that the amounts will be based on their actual monthly salary and fringe benefits and prorated accordingly. Students' salaries should be based on the prevailing scale for comparable type work, but should not be less than the Federal minimum hourly wage. Funds to defray other costs such as supplies can be requested as a lump sum of up to \$250 per participant per year.

RESEARCH OBJECTIVES

Background

Relative to their representation in the general population, minority Americans are severely underrepresented in scientific and health fields at every level, from the professional work force - physicians, dentists, research scientists - through all levels of the educational system. Although there are a number of factors for this underrepresentation, it is generally agreed that the long-term resolution of this problem centers at improving science education of minority youths at the early stages of the educational process.

With the rapid pace of technological innovations and the increasing number of occupations that require a knowledge of scientific principles, as well as the predicted increase in the minority population, it is imperative that precollege education further enhance the capacity and capability of minority youth to become more productive and competitive in tomorrow's work force. The primary objectives of this program are to improve the quality of precollege science education and to increase the pool of minorities interested and prepared to enter college and pursue a career in the biomedical/behavioral sciences.

Program Characteristics

The Program Director will be responsible for the selection and recruitment of students, teachers, and mentors, as well as for the overall direction of the program. The program director must be a biomedical/behavioral scientist or an experienced science educator employed by the applicant organization.

The program has two major activities. The first is for minority high school students; the second is for K-12 inservice and preservice teachers. While the proposed program should be best suited to an institution's own strengths and characteristics, at a minimum, each program should include:

- o a description of the proposed overall program plan (specific research projects should not be described);
- o a description of the research environment (ongoing research activity, availability of equipment, facilities, resources);

- o methods and criteria for student, teacher, and mentor recruitment and selection;
- o methods to assign students and teachers to mentors;
- o the length of the research experiences;
- o other special enrichment activities available to students and teachers;
- o plans to evaluate program progress;
- o prior accomplishments of the institution in precollege education;
- o the impact of other precollege programs, if any, for the proposed program; and
- o the level of institutional commitment to precollege programs and partnerships.

Criteria for selection of mentors must include: commitment to improving the quality of precollege science education, the ability and time to work with high school students and teachers to instill an understanding of research and the technical skills needed. Mentors must have active biomedical or behavioral research support and/or a recent publication history in biomedical/behavioral research. Research support can include NIH or other Federal agency support or private or institutional grants.

An evaluation component must be included as part of the application. Methods, formative in nature, should be devised to evaluate whether or not the program is making progress in meeting the program goals. For example, information should be collected to learn if the program is helping teachers integrate new concepts in health sciences into the classrooms. Student participants should be assessed to determine if it has increased their awareness and/or interest in the health sciences. To the extent possible, students should be followed to determine if they attended and/or graduated from college and, if so, their major academic area of concentration.

Specific characteristics regarding the student and teachers activities are as follows.

Student Activities

The most important aspect of this program is the research laboratory experience. The program provides for matching high school students for approximately six to eight weeks in the summer, with a ratio of not more than two students to one mentor, in an active research laboratory.

It is expected that the applicant will describe a research program that will provide:

- o an independent, hands-on, mentored laboratory experience with attainable goals which introduces the students to some of the latest concepts in biomedical science;
- o mentoring and career guidance by biomedical/behavioral scientists;
- o an opportunity for students to participate in various laboratory activities and acquaint them with the environment and resources of the institution.

A program of special summer scientific enrichment activities must be proposed. Such activities may include, but are not limited to: programs on research opportunities and careers within the health sciences, bioethical issues in biomedical/behavioral research or implications of the human genome effort. A final forum should be held where students present their research results.

In order to maximize the long-term effects of the summer experience, follow-up activities such as seminars, workshops or Saturday study groups may occur during the academic year if the students are located within reasonable distance of the research institution. Mentors should also try to visit students' schools to meet with teachers, recruit future candidates for the program and help build effective partnerships between the research institutions and secondary schools.

Recruitment and selection criteria for students should include: the student's motivation, ability, scholastic aptitude, and accomplishments. In addition, consideration should be given to science teachers' recommendations.

Teacher Activities

K-12 teachers are the key individuals in increasing the pool of scientifically skilled minority high school students. However, most preservice teaching programs do not require a hands-on laboratory experience; most elementary school teachers have had no opportunity for training in science; and most middle, junior, and senior high school teachers need retraining in the latest scientific concepts.

To address these deficiencies, the proposed program should provide inservice and preservice teachers with an intensive hands-on mentored laboratory research experience of four weeks or more that:

- o exposes them to contemporary concepts in the health sciences
- o introduces them to modern laboratory techniques, including computers;
- o enables them, in collaboration with their research mentor, to prepare new discovery-based lesson plans.

Unless the teachers' schools are geographically remote, the teacher programs must include follow-up components in which the participants discuss their experiences in implementing new scientific activities into the classroom. An important aspect of the program is to develop continuing partnership relationships between teachers and mentors to improve the teaching of life sciences at the precollege level and to stimulate students interest in health science careers.

Recruitment and selection criteria for inservice teachers should include: experience and teaching responsibilities, level of interest in participating in a research program, expected impact on their teaching programs, ability to stimulate

minority students to pursue scientific careers, and future plans for continued interaction with the research institution.

Recruitment and selection criteria for preservice teachers should include the commitment to participate in a research program and the expressed interest to teach life sciences at the K-12 level with a focus on minority students.

APPLICATION PROCEDURES

Applications are to be submitted using form PHS 398 (rev. 9/91). These forms are available in most institutional offices of sponsored research and may be requested from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

Applications must follow the instructions provided in the PHS 398 form except for the following:

Form Page 1

Item 2a. - Identify the number and title of this program announcement and check the box marked "YES."

Item 2b. - Type "R25" in 2b.

Item 4. Human Subjects - Not relevant (no project description).

Item 5. Vertebrate Animals - Not relevant (no project description).

Item 6. The project period start date should be 04-01-95. The length of the project period may not exceed three years.

Form Page 4 - Detailed Budget for Initial Budget Period.

Personnel Category - Follow the instructions provided in the PHS 398 regarding the Principal Investigator/Program Director. Using successive lines in the Personnel Category, indicate the number of positions being requested for students, preservice, and inservice teachers. For each of these classifications, provide requested information regarding type of appointment/months, percent of effort on project, and institutional base salary, as well as the dollar amounts being requested. Salary and fringe benefit support may be requested only for the students and teachers.

Other Expenses - Up to \$250 per student and teacher participant may be requested as a lump sum to defray costs such as supplies required for their research experiences.

Form Page 5 - Budget for the Entire Proposed Project Period - Follow instructions provided on page 19 of the PHS 398 kit.

Justification - Applicants should provide sufficient information regarding the support requested for students, preservice, and inservice teachers to permit the reviewers to evaluate the requested costs compared to the proposed length of the research experience. If the proposed program includes academic year as well as summer involvement, provide separate budgetary justification regarding each.

Applicants should also explain any increases or decreases over the initial budget period, e.g., if students and/or teachers are expected to return for a portion of a succeeding period and will require salary and other support during this period.

Additional Form Pages

Biographical Sketch Page - Provide a biographical sketch for the Program Director and each proposed mentor, strictly adhering to the 2 page limitation for each.

Other Support Page - Provide the information requested for the Program Director and each proposed mentor.

Resources and Environment Page - Follow the PHS 398 instructions.

Specific Instructions - Research Plan

The following instructions should be used in lieu of the PHS 398 instructions for this section of the application. The Research Plan section of the application must strictly adhere to a limit of 15 pages, excluding a maximum of three letters of institutional support. Include sufficient information to facilitate an effective review; be specific, informative, and avoid redundancies. The outline suggested below should be followed in describing the program.

A. Background

If the applicant institution has held a MHSSRAP grant in the past, describe the history of the program, the type and size of the program (number of students and teachers) and any program accomplishments including tracking data for the students, if available. Information may be provided in tabular form. Prior accomplishments of the institution in other precollege science activities may also be included.

B. Proposed Program

At a minimum, provide information regarding:

1. A description of the proposed program;
2. A description of the research environment and how it relates to the proposed program (e.g., ongoing research activity, availability of equipment, facilities, and resources);

3. Methods and criteria for student, teacher, and mentor recruitment and selection;
4. Methods to assign students and teachers to mentors (specific research projects should not be described) but a description of the general scientific skills to be learned should be included;
5. The length of the student, preservice, and inservice teacher research programs;
6. Other special enrichment activities available to the students and teachers;
7. Plans for formative evaluation of the program.

C. Institutional Supporting Data

Include a minimum of one and a maximum of three letters of institutional support. The letter(s) should be from a highly placed institutional official, at the level of Dean or above, who is in a position to commit the institutional resources necessary to assure effective conduct of the program.

Appendix - No appendix material will be allowed.

The signed, typewritten original of the application, including the Checklist, and three exact photocopies of the signed application must be submitted to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At time of submission, two additional copies of the application must also be sent to:

Dr. Marjorie A. Tingle
Biomedical Research Support Program
National Center for Research Resources
Westwood Building, Room 848
Bethesda, MD 20892

Applications must be submitted by September 12, 1994. Applications submitted after this date will be returned to the applicant.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by the NCRR. Incomplete applications will be returned to the applicant without further consideration. If staff find that the application is not responsive to this program, it will be returned without further consideration.

Applications that are complete and responsive to this program announcement will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NCRR in accordance with the review criteria stated below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to this program announcement. Applications judged to be competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the principal investigator/program director and the official signing for the applicant organization will be promptly notified.

Criteria for review of applications include the following:

- o quality of the overall scientific and educational content of the proposed program including research laboratory and special enrichment activities;
- o appropriateness of the plans considering the size, strengths, and characteristics of the institution;
- o the qualifications of the Program Director and the proposed mentors;
- o the quality of the method of recruitment, selection and assignment of students, teachers, and mentors;
- o the quality of the institution's plans for a formative evaluation of the program;
- o the extent of the institutional commitment to providing a quality research experience and to precollege education partnerships; and
- o the extent of prior accomplishments in precollege education.

The second level of review will be provided by the National Advisory Research Resources Council in February 1995.

AWARD CRITERIA

The following will be considered when making funding decisions: the quality of the proposed application as determined by peer review, availability of funds, program balance among the types of institutions and geographic distribution of the awards.

INQUIRIES

Written and telephone inquiries concerning this PAR are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Dr. Marjorie A. Tingle or Dr. Abraham Levy
Biomedical Research Support Program
National Center for Research Resources
Westwood Building, Room 848
Bethesda, MD 20892
Telephone: (301) 594-7947

Direct inquiries regarding fiscal matters to:

Ms. Mary V. Niemiec
Office of Grants and Contracts Management
National Center for Research Resources
Westwood Building, Room 849
Bethesda, MD 20892
Telephone: (301) 594-7955

AUTHORITY AND REGULATIONS

Awards will be made under authorization of the Public Health Service Act, Title III, Part A (Public Law 78-410, as amended, 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements for Executive Order 12372 or Health Systems Agency review.

ERRATA

OBESITY/NUTRITION RESEARCH CENTERS

NIH GUIDE, Volume 23, Number 26, July 15, 1994

RFA: DK-94-020

P.T. 04; K.W. 0710095, 0715145, 0710030, 1002004, 0765020

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: October 21, 1994

Application Receipt Date: November 22, 1994

The following change is made to RFA DK-94-020, which was published in the NIH Guide for Grants and Contracts, Vol. 23, No. 19, May 20, 1994:

On May 20, 1994, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) published RFA DK-94-020 which invited applications for Obesity/Nutrition Research Centers (ONRCs) to conduct basic and clinical research on obesity, and the related fields of energy metabolism, body composition, satiety, adipocyte metabolism, eating disorders and weight management. RFA DK-94-020 stated that the NIDDK anticipated making one award as a result of that RFA. The NIDDK now anticipates awarding two ONRC grants instead of one, assuming that applications with sufficient merit are received.

INQUIRIES

Applicants may obtain additional information from:

Van S. Hubbard, M.D., Ph.D.
Division of Digestive Diseases and Nutrition
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A18B
Bethesda, MD 20892
Telephone: (301) 594-7573
FAX: (301) 594-7504

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

***5333 Westbard Avenue
Bethesda, MD 20816***

J

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RICHARD W MURRY

* 340189
S1350E

929 WILD FOREST DRIVE
GAITHERSBURG MD 20879 3209

Vol. 23, No. 27
July 22, 1994

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

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EXTENSION OF PROGRAM ANNOUNCEMENT EXPIRATION DATES

NIH GUIDE, Volume 23, Number 27, July 22, 1994

P.T. 34; K.W. 0408006, 0730050, 0730020

Agency for Health Care Policy and Research

PURPOSE

The Agency for Health Care Policy and Research (AHCPR) announces the extension of the expiration dates to: (1) July 1, 1995 for the "Cost and Financing Issues in Health Care Reform" program announcement (PA-93-045), printed in the NIH GUIDE, Volume 22, Number 4, January 29, 1993; and (2) July 1, 1996 for the "Primary Care and Health Care Reform" program announcement (PA-93-063), printed in the NIH GUIDE, Volume 22, Number 10, March 12, 1993.

Copies of these updated PAs and other AHCPR announcements are available from Global Exchange Inc., 7910 Woodmont Ave Suite 400, Bethesda, MD 20814-3015, telephone 301-656-3100 (FAX 301-652-5264).

INQUIRIES

For programmatic information on the "Cost and Financing Issues in Health Care Reform" PA, contact:

Michael Hagan
Division of Cost and Financing
Agency for Health Care Policy and Research
Executive Office Center, Suite 502
2101 East Jefferson Street
Rockville, MD 20852-4908
Telephone: (301) 594-1354 ext. 124

For programmatic information on the "Primary Care and Health Care Reform" PA, contact:

Carolyn Clancy, M.D., Director
Division of Primary Care
Agency for Health Care Policy and Research
Executive Office Center, Suite 502
2101 East Jefferson Street
Rockville, MD 20852-4908
Telephone: (301) 594-1357 ext. 133

NOTICES OF AVAILABILITY (RFPS AND RFAs)

RESEARCH ON PERIODONTAL COMPLICATIONS OF DIABETES MELLITUS

NIH GUIDE, Volume 23, Number 27, July 22, 1994

RFA AVAILABLE: DE-94-008

P.T. 34; K.W. 0715075, 0715157, 0765033, 0755030

National Institute of Dental Research
National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: October 21, 1994
Application Receipt Date: November 22, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA). IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Dental Research (NIDR) and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invite investigator-initiated grant applications to conduct multidisciplinary basic and clinical research on the periodontal complications of diabetes mellitus (DM). One purpose of this initiative is to further our understanding of the pathogenesis of periodontal diseases associated with DM. Another purpose is to increase research on the effects of periodontal diseases on glucose metabolism in diabetics. Investigators who are well-trained in the modern techniques of cellular and molecular biology are encouraged to focus their expertise and work closely with oral clinicians on issues directly related to the diagnosis, etiology, pathogenesis, and treatment of periodontal diseases associated with DM.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Research on Periodontal Complications of Diabetes, is related to the priority areas of oral health and diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, non-profit, and for-profit, public and private organizations, such as dental or medical schools, universities and research institutions. Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) (R29) Award. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The mechanisms available for the support of research in response to this RFA are the traditional research project grant (R01), and the FIRST (R29) Award. The project period for applications submitted in response to this RFA may not exceed five years for R29 grants and four years for R01 grants. A maximum of three years may be requested for foreign awards. R01 applicants must limit their request to not more than \$160,000 direct costs for the initial budget period.

FUNDS AVAILABLE

For Fiscal Year 1995, \$1.2 million total costs will be committed by the NIDR and NIDDK to fund applications submitted in response to this RFA. Approximately five awards will be made depending on the receipt of a sufficient number of applications of high scientific merit.

RESEARCH OBJECTIVES

Background

Diabetes may affect the progression and treatment of periodontal diseases. In particular, the incidence of aggressive and difficult to treat forms of periodontitis is well-documented in patients with DM. Epidemiological studies have clearly shown that periodontal diseases tend to be more prevalent, more severe, and progress more rapidly in persons with diabetes than in non-diabetic subjects. Periodontitis is now recognized as one of the six major complications of diabetes. It appears that although all diabetics may be at a higher risk for periodontal diseases than the general population, certain subgroups are at particularly high risk, including individuals who do not maintain good oral hygiene, individuals with other complications of diabetes such as retinopathy, neuropathy, or individuals with a history of poorly controlled diabetes, and teenagers and pregnant women undergoing fluctuations in hormonal levels. A detailed epidemiological analysis of periodontitis and tooth loss in the Pima Indians showed that the incidence of diabetes-specific complications, poor glycemic control, and severity of Type 2, non-insulin dependent diabetes mellitus (NIDDM) are associated with increased risk of periodontitis. The prevalence of periodontal diseases in well-controlled diabetics is reportedly no higher than that found in healthy control subjects. The molecular and cellular basis for the pathogenesis of periodontal diseases in uncontrolled DM patients remains to be investigated.

Oral infections associated with periodontitis may destabilize the metabolic balance of the diabetic. Diabetics with infections tend to have difficulty in maintaining normal blood glucose/insulin levels, and often experience hyperglycemia. Understanding the association between infections in the oral cavity and impaired metabolic control is central to attaining effective therapy for the diabetic patient.

Scope

Applications may address any objective that would advance the diagnosis, etiology, pathogenesis or treatment of periodontal complications of diabetes. Applications may also address the role of periodontitis in metabolic control of the diabetic. Because research in this area can involve several scientific specialties, including microbiology, immunology, physiology, endocrinology, cell biology, and clinical medicine and dentistry, collaboration of investigators having expertise in these and other appropriate disciplines is encouraged. Large-scale epidemiological studies and clinical trials are specifically excluded from this RFA.

Because Type 1, insulin-dependent diabetes mellitus (IDDM) and NIDDM are pathologically and genetically different, studies that examine the molecular and cellular basis of periodontal complications of both types of diabetes are encouraged.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by October 21, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of this RFA.

The letter of intent is to be sent to Dr. Dennis Mangan at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research, as well as from the Office of Grants Information, Division of Research Grants (DRG), National Institutes of Health, Westbard Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. See the RFA for further information.

Submit a signed, original copy of the application, and three signed photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Also send two copies of the completed application to:

H. George Hausch, Ph.D.
National Institute of Dental Research
Westwood Building, Room 519
Bethesda, MD 20892
Telephone: (301) 594-7632
FAX: (301) 594-7601

Applications must be received by November 22, 1994.

REVIEW CONSIDERATIONS

Applications that are complete and responsive to the RFA will be evaluated by an appropriate peer review group convened by the NIDR in accordance with the usual NIH peer review procedures. Following review, the applications will be given a secondary review by the NIDR and NIDDK Advisory Councils unless not recommended for further consideration by the initial review group. Applications that are incomplete or unresponsive to the RFA will be returned to the applicant.

AWARD CRITERIA

The anticipated award date is September 1, 1995. In addition to the technical merit of the application, the NIDR and NIDDK will consider support of applications based on availability of funds and program priorities of the funding ICD.

INQUIRIES

The RFA may be obtained electronically through the NIH Grant Line (data line 301-402-2221) and the NIH GOPHER via Internet, and in print form from the program contact listed below.

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Direct inquiries regarding programmatic issues, requests for the RFA, and the letter of intent to:

Dennis F. Mangan, Ph.D.
National Institute of Dental Research
Westwood Building, Room 509
Bethesda, MD 20892
Telephone: (301) 594-7641
FAX: (301) 594-9720
Email: UFD@CU.NIH.GOV

Dr. Charles A. Wells
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 622
Bethesda, MD 20892
Telephone: (301) 594-7505
FAX: (301) 594-9011

Direct inquiries regarding fiscal matters to:

Ms. Theresa Ringler
Extramural Program
National Institute of Dental Research
Westwood Building, Room 510
Bethesda, MD 20892
Telephone: (301) 594-7629
FAX: (301) 594-7600

Ms. Betty E. Bailey
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 649
Bethesda, MD 20892
Telephone: (301) 594-7543
FAX: (301) 594-7594

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.121. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, (42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NIH GUIDE, Volume 23, Number 27, July 22, 1994

RFA AVAILABLE: CA-94-013

P.T. 34; K.W. 0745003, 0765014, 0760020, 0740020

National Cancer Institute

Letter of Intent Receipt Date: October 15, 1994

Application Receipt Date: November 23, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites applications for cooperative agreements to stimulate and facilitate investigator initiated chemoprevention research involving agents that may effect gene expression and cellular growth and to encourage development of short-term clinical trials that evaluate the modulation/function of gene products by chemoprevention agents.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Chemoprevention Clinical Trials Involving Modulation/Function of Genes and/or Gene Products, is related to the priority area of chemoprevention. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications from minority individuals and women investigators are encouraged.

Each application will be considered on its own merit as an individual research project. Applicants for "Chemoprevention Clinical Trials Involving Modulation/Function of Genes and Gene Products" MAY NOT concurrently submit R01 applications that represent significant duplication of the efforts.

MECHANISM OF SUPPORT

This RFA will use the cooperative agreement (U01) mechanism. The cooperative agreement is an assistance mechanism in which substantial NIH programmatic involvement with the recipient during performance of the planned activity is anticipated. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant/awardee. Details of the responsibilities, relationships and governance of the study to be funded under cooperative agreement(s) are discussed in the RFA.

Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the sizes of awards will vary also.

This RFA is a one-time solicitation. Future unsolicited competitive continuation applications will compete with all other investigator-initiated research applications and be peer reviewed by a study section in the Division of Research Grants (DRG), NIH. However, if it is determined that there is a sufficient continuing need, the NCI will invite recipients of awards made in FY 95 under this RFA to submit competitive continuing applications.

Applicants funded under this RFA will be supported through the cooperative agreement mechanism. An assistance relationship will exist between NCI and the awardees to accomplish the purpose of the activity. The recipients will have primary responsibility for the development and performance of the activity. However, there will be government involvement with regard to (1) assistance in securing an Investigational New Drug (IND) approval from the Food and Drug Administration (FDA), (2) coordination and assistance in obtaining the chemopreventive agent, (3) monitoring of safety and toxicity, and (4) quality assurance of the clinical chemistry aspects of the study. If an investigator anticipates requiring considerable assistance in obtaining the chemopreventive agents or in securing the Investigational New Drug (IND) permit, from the Food and Drug Administration, such assistance must be sought in writing from the Program Director, prior to submitting the application. Awards will not be made until all arrangements for obtaining the IND and the agent are completed. Final awards will also consider not only the cost of the clinical trial, but also the cost of the agent and its formulation.

FUNDS AVAILABLE

Approximately \$2.0 million in total costs per year for five years will be committed to specifically funded applications that are submitted in response to the RFA. It is anticipated that three to six awards will be made. The number of awards is dependent on the receipt of a sufficient number of applications of high scientific merit. The total project period for an application submitted in response to the present RFA may not exceed five years. The earliest feasible start date for the initial awards will be July 1995. Although this program is provided for in the financial plans of the NCI, awards made pursuant to this RFA will be contingent upon the continued availability of funds for this purpose.

Evolving understanding of molecular mechanism brings unprecedented opportunities for advances in the prevention of cancer based especially on the identification of specific gene products and the modulation of their effects at the molecular level with chemopreventive agents. New developments in the understanding of cellular function and cellular metabolites are occurring that provide information on cell growth, proliferation, differentiation and neoplastic transformation.

The endpoints for cancer treatment trials are usually a measured reduction in tumor size or statistically measured survival in a population whose survival is limited. For chemopreventive interventions, no such easily measured endpoints exist. For a clinical endpoint, the primary endpoint is incidence reduction, which occurs years later. Complex biostatistical and epidemiological strategies are necessary in measuring study populations in order to prove efficacy. Another approach is to develop surrogate endpoints to measure effect and for the study of the carcinogenesis process in humans.

Inhibition of the post initiation phases of carcinogenesis is an emerging strategy for the prevention of cancer. Recent understanding of the role of oncogenes and tumor suppressor genes in cancer development suggests several strategies. Specifically, gene products appear to act at various points in the intracellular pathway utilized by growth factors, cell surface receptors, GTP-binding proteins, protein kinases, and transcription factors in stimulating cell proliferation. A common characteristic of these genes is that they encode components of the signal transduction system. This system refers to the biochemical mechanisms that permit complex changes in the cytoplasm and in gene expression in the nucleus which are often controlled by extracellular ligands that act through receptors, second messenger molecules and protein kinases. Clinical trials of agents effecting gene expression or gene products are being sought.

The goal is the development of short-term clinical trials that will evaluate the modulation/function of genes or gene products by chemopreventive agents. The studies should be developed in phases that may include a pilot phase in humans that could later proceed to a full-scale intervention. One or more biomarker endpoints might be initially evaluated to determine baseline parameters and, subsequently, to serve as a follow-up after the administration of the prevention measure or the chemopreventive agents in vivo and/or in vitro. The main emphasis should be on small, efficient studies aimed at improving future research designs, providing a molecular basis for the action of the chemopreventive agent(s), or providing improved intermediate endpoint biomarkers. After successful completion of the pilot phase (i.e., demonstrated modulation of endpoint biomarkers), subsequent studies could include a clinical trial monitoring the test system, a cancer incidence or mortality endpoint, and a designated agent. Studies that develop and evaluate biotechnologies for the identification of new genes, gene products and DNA probes to identify human disease or to identify individuals at high risk or predisposition to cancer are also encouraged.

For the initial human phase, the proposed study might describe the relevance of the marker test system to clinical or public health cancer prevention, the rationale for the selection of the study population, potential intervention agent or procedure. The project could result, later, in the markers and agent being evaluated in a full-scale, double-blind, randomized, risk reduction clinical trial. See RFA for further details.

SPECIAL REQUIREMENTS

Special requirements will be incorporated in the "Terms and Conditions of Award." Potential applicants should obtain a copy of the RFA to review these requirements prior to submission of their application.

SPECIAL POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by October 15, 1994, a letter of intent that includes a descriptive title of the proposed research, the name and address of the principal investigator, the names of other key personnel, the participating institution or institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NCI staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to Dr. Winfred F. Malone at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The regular research grant application form, PHS 398 (rev. 9/91) is to be used in applying for these cooperative agreements. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 302/594-7248; and from the NCI Program Director listed under INQUIRIES.

The RFA label available in the PHS 398 (rev. 9/91) must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the title of the application, "Chemoprevention Clinical Trials Involving Modulation/Function of Genes and/or Gene Products," and the RFA number, CA-94-013, must be typed in block 2a of the face page of the application form.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, exact, clear, and single-sided photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission two additional copies of the application must also be sent to:

Ms. Toby Friedberg
Division of Extramural Activities
National Cancer Institute
Executive Plaza North, Room 636
Rockville, MD 20852 (if hand delivered or delivery service)
Bethesda, MD 20892 (if using U.S. Postal Service)

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by the NCI. Incomplete applications will be returned to the applicant without further consideration. If NCI staff find that the application is not responsive to the RFA, it will be returned without further consideration.

Applications that are complete are responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NCI in accordance with the review criteria stated below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA. Applications judged to be competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the principal investigator/program director and the official signing for the applicant organization will be promptly notified.

The review criteria are provided in the RFA.

AWARD CRITERIA

The earliest feasible start data for the initial awards will be July 1, 1995. In addition to the technical merit of the applications, in making funding decisions. NCI will consider how well the applicant institutions meet the goals and objectives of the program as described in the RFA, availability of resources, and study populations.

INQUIRIES

Written and telephone requests for this RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Winfred F. Malone, Ph.D., M.P.H.
Division of Cancer Prevention and Control
National Cancer Institute
Executive Plaza North, Suite 218
Bethesda, MD 20892
Telephone: (301) 496-4664
FAX: (301) 402-0553

Direct inquiries regarding fiscal matters to:

Robert Hawkins
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Suite 234
Bethesda, MD 20892
Telephone: (301) 496-7800

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, Number 93,399, Cancer Control. Awards will be made under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-401; 42 U.S.C. 241, and Section 412, as amended by Public Law 99-158, 42 U.S.C. 258-1), and administered under PHS grants policies and Federal regulations 42 CFR, Part 52 and 45 CFR, Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

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RFA AVAILABLE: HD-94-021

P.T. 04, AA; K.W. 0710030, 0770005, 0785170

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: October 1, 1994

Application Receipt Date: January 18, 1995

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Child Health and Human Development (NICHD) invites Center Core Grant applications for a program of Child Health Research Centers (CHRC). These Centers are intended to provide resources to speed the transfer of knowledge gained through studies in basic science to clinical applications that will benefit the health of children. This will be accomplished by increasing the number of pediatric medical centers that can stimulate and facilitate the application of research findings to pressing pediatric problems, as well as increasing the number and effectiveness of pediatric investigators who have a grounding in basic science and research skills that can be applied to the clinical problems of children.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Child Health Research Centers, is related to several priority areas. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

A CHRC grant is an award made to a children's hospital or to a department of pediatrics of an approved medical school in the United States of America that has as a primary teaching site either a general acute children's hospital or a children's program with an identifiable organizational structure that is part of a larger medical institution. Either must have the clinical pediatric specialties and subspecialties and the discrete clinical and research facilities sufficient to ensure the linkage of basic research and clinical application that will meet the purposes of the CHRC program. The applicant institution must also meet the standard eligibility requirements for research grants established in the PHS Grants Policy Statement (rev. 4/94).

MECHANISM OF SUPPORT

Support for this program will be through Center Core Grant (P30) awards. Policies that govern the grants award programs of the PHS will prevail. The support of grants pursuant to the RFA is contingent upon the receipt of appropriated funds for this purpose. Applications from institutions not previously funded for Child Health Research Centers will compete on an equal basis with competing continuation applications. This RFA is a one-time solicitation. Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of an award will vary also.

FUNDS AVAILABLE

The estimated total cost available for the first year of support is \$2,400,000. It is anticipated that six or more meritorious applications (new and competing continuation) will be funded from responses to this RFA. The maximum amount will be \$400,000 for direct plus indirect costs in the first year, with no increases for inflation in subsequent years. The number of awards will be influenced by the overall merit of applications and by their relevance to program goals.

RESEARCH OBJECTIVES

The past several years have seen unprecedented advances in the power and speed of basic science methods applicable to investigations of inherited and acquired disease. There is a need for researchers who are skilled with these methods and are interested in applying them to clinical problems in pediatrics. The NICHD has begun to meet this need by establishing Centers in which nascent pediatric investigators can develop the appropriate technological expertise.

A CHRC grant provides pediatric research institutions, both developing and established, an opportunity to build a greater capacity for nurturing new pediatric investigators. Established investigators whose research is already funded by NIH or other sources through competitively reviewed grants or contracts combine to establish in their institution a center of research excellence. Individuals with a wide range of scientific backgrounds, especially those with basic science orientation, are encouraged to interact with each other and with newly trained pediatricians just embarking on their research careers. A shared core laboratory, which provides services to complement and extend the capabilities of the established investigators to facilitate the career development of new investigators, may be a major part of the Center. The established investigators make available their expertise, guidance, and laboratory facilities, which together with the shared core laboratory comprise the laboratory resources of the Center, to be utilized by junior investigators for new research projects which will enhance their basic science knowledge and skills. Support for conducting these projects is provided by the Center.

The CHRC grant may provide funds for three purposes:

A. Administration of the Center.

B. Improvements in the child health-related research program of an institution in an area of scientific excellence through the establishment and maintenance of a shared core laboratory.

C. Support for new projects, conducted by junior investigators, designed to enhance their research skills and produce preliminary data which could lead to successful competitive grant applications to the NIH or other agencies (New Project Development Funds), thereby providing a bridge between formal research training and the receipt of independent research grants.

The novel feature of these grants is the flexibility in the use of the funds awarded for research support and career development, so that decisions about which new projects and which junior investigators are to be supported are made by the grantee institution. Both competing continuation (renewal) and noncompeting continuations of a CHRC grant are contingent on demonstration of good judgment in these decisions, as indicated by scientific progress, success in the initiation of new competitively-supported research grants and contracts, and the development of new pediatric investigators.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by October 1, 1994, a letter of intent that includes a descriptive subtitle for the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NICHD staff to estimate the potential review workload, to seek out appropriate reviewers, and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to Dr. Ephraim Levin at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91). These forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248. Applications must be received by January 18, 1995. Potential applicants must request the detailed information included in the RFA before preparing an application.

REVIEW CONSIDERATIONS

Applications will be reviewed by NICHD staff for responsiveness to the RFA. A non-responsive application will be returned to the applicant. Responsive applications may be subjected to a triage by a peer-review group to determine their scientific merit relative to the other applications received in response to this RFA. The NICHD will withdraw from competition those applications judged to be noncompetitive and notify the applicant and institutional business official.

AWARD CRITERIA

The anticipated date of award is September 1, 1995, based on the following timetable:

Letter of Intent Receipt Date:	October 1, 1994
Application Receipt Date:	January 18, 1995
Initial Review Date:	March 1995
Review by Advisory Council:	June 1995

Scientific merit and technical proficiency, based on the demonstrated and projected capabilities described in the application will be the predominant criteria for determining funding priorities.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions for potential applicants are encouraged.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Ephraim Y. Levin, M.D.
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
6100 Building, Room 4B11
Bethesda, MD 20892
Telephone: (301) 496-5593

Direct inquiries regarding fiscal matters to:

Ms. Mary Ellen Colvin
Office of Grants and Contracts
National Institute of Child Health and Human Development
6100 Building, Room 8A17
Bethesda, MD 20892
Telephone: (301) 496-1303

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.865, Research for Mothers and Children. Awards are made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

DEVELOPING AND IMPROVING INSTITUTIONAL ANIMAL RESOURCES

NIH GUIDE, Volume 23, Number 27, July 22, 1994

PA NUMBER: PAR-94-083

P.T. 34; K.W. 1002002

National Center for Research Resources

Application Receipt Dates: October 1, February 1, June 1

PURPOSE

The National Center for Research Resources (NCRR) encourages the submission of individual animal resource improvement grant applications from biomedical research institutions. The major objectives of this program are to upgrade animal facilities, develop administratively centralized programs of animal care, and enable institutions to comply with the USDA Animal Welfare Act and DHHS policies related to the care and use of laboratory animals. Support is limited to alterations and renovations (A&R) to improve laboratory animal facilities, and the purchase of major equipment items for animal resource, diagnostic laboratory, transgenic animal resources, or similar associated activities.

ELIGIBILITY REQUIREMENTS

Any domestic public or private institution, organization, or association is eligible to apply for this grant if the institution has one or more research projects supported by the Public Health Service (PHS) that involve the use of laboratory animals. Institutions and commercial firms providing only services or products and without a clearly defined animal related research component are not eligible to apply. Also, this program will not support requests for equipment used for teaching purposes and for housing non-research animals. Applications from other Federal agencies or institutions (e.g., Department of Veterans Affairs) are limited to requests for equipment only. Applicants may not submit more than one application or apply for other NCRR support for developing and improving institutional animal resources in the same Federal fiscal year.

For purposes of these guidelines, an "institution" is defined as the organizational component identified on page 1, item 14 of the PHS 398 (rev. 9/91), for which descriptive information is provided on page 15 in the grant application form PHS 398 kit. Separate applications may be submitted from different colleges or schools on the same campus of a university within the same Federal fiscal year if they have different organizational component codes. If this is done, documentation from an appropriate institutional official, stating that the applications are part of a coordinated, campus-wide plan to improve the animal facilities, must be provided. The applicant institution is strongly encouraged to develop a single application for a campus-wide program with a single, centralized animal care program whenever possible or feasible.

MECHANISM OF SUPPORT

The mechanism available for the support of improvement projects is the Grant for Repair, Renovation, and Modernization of Existing Research Facilities (G20). The total budget request for the improvement grant application and award is limited to \$700,000 (direct costs), of which not more than \$500,000 may be used for alterations and renovations. Matching funds from non-Federal sources are required, equal to or exceeding one-third of the total allowable costs (equipment and A&R) of the requested project (\$2 Federal to \$1 non-Federal). These matching funds must be applied to the specific project described in the application and cannot be met by citing other expenditures.

Because the nature and scope of the projects proposed in response to this PA may vary, it is anticipated that the size of an award will vary also.

Allowable Costs

Items that may be requested under this grant mechanism include:

- o A&R to improve existing laboratory animal facilities, and allowable fees associated with the A&R project
- o Major resource equipment related to the improvement project, such as animal cage systems and cage washers
- o Equipment items, or an aggregate of identical equipment items, that have a total cost of at least \$1,000. Items that are part of a system and require the purchase of small component parts (e.g., a rack and cages or microisolator units)

may be requested and priced as a single item. A description of the individual components of such systems must be provided.

- o General purpose equipment items for centralized surgeries, diagnostic laboratories, transgenic animal facilities, and other similar associated activities when an integral part of the animal facility and available to all investigators
- o Basic diagnostic equipment (e.g., microscopes, centrifuges, refrigerators, etc.) to be used in support of the animal facility, but not for research
- o Environmental monitoring systems. However, if such a system has multiple uses (e.g., the monitoring of research data or security), only those costs related to monitoring or providing for animal care (e.g., environmental monitoring) are allowable

Improvement grants are not intended to provide support for:

- o General operational support for the resource (e.g., funding for personnel, consumable supplies for routine animal care, or small equipment items)
- o Specialized research equipment or facilities for use by only a few investigators
- o New construction, including the completion of shell space
- o Equipment intended for teaching or non-research purposes
- o Office and research equipment, computers or data processing items
- o Physical security systems

RESEARCH OBJECTIVES

Animal resource improvement grants are awarded to assist biomedical research institutions in upgrading animal facilities and developing administratively centralized and uniformly effective programs of research animal care. Another major objective is to assist institutions in complying, and maintaining compliance, with provisions of the Animal Welfare Act and PHS policies related to the care and use of laboratory animals.

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91). Application forms may be obtained from the institution's office of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. There are three regular receipt dates per year of October 1, February 1, and June 1.

Prospective applicants are encouraged to review the PHS Grants Policy Statement (rev. 4/94) sections dealing with alterations and renovations and equipment prior to completing the PHS 398 form.

Applications must follow the instructions provided in the form PHS 398 kit, except for the following:

Form Page 1:

- Item 2a - Check the box marked "YES" and type in the number and title of this program announcement.
- Item 2b - Insert "G20"
- Item 5 - Check the box marked "No" at Item 5a. Item 5b - Not applicable.

Form Page 2:

Personnel - Only key personnel should be listed here even though salary support is not requested. This must include the chief or consulting veterinarian.

Form Page 4: Detailed Budget for Initial Budget Period

Personnel Category - List only key individuals; salary support should not be requested.

The total cost of the equipment and A&R needed should be entered in the rectangular space under the appropriate headings on the left. Equipment should be classified as movable or fixed, using the institution's own classification guidelines. Fixed equipment is considered as part of the A&R request. The right hand column should reflect only the PHS request. The Total Direct Costs (bottom right hand column total) should be the total request to the PHS. The total request for PHS support may not exceed \$700,000. Of this total, the A&R request may not exceed \$500,000.

Form Page 5 - Budget for Entire Proposed Project Period - Not applicable (do not complete this section).

A cost estimate should be provided, and placed after Form Page 4. This estimate should detail:

1. For movable equipment, the dollar request from NIH, amount to be funded from other sources, and total cost.
 2. For eligible A&R costs, the dollar request from NIH, amount to be funded from other sources, and total cost.
 3. For total project cost, the dollar request from NIH, amount to be funded from other sources, and total cost.
- For funding from other sources, please indicate the source(s).

For alterations and renovations requests, list separately the projected costs of: (a) Demolition; (b) General; (c) Plumbing; (d) HVAC; (e) Electrical; (f) Architect/Engineer Fee; (g) Other Costs c(Specify); and (h) Fixed Equipment, with the total eligible A&R costs listed. If multiple sites are involved, the A&R and cost estimates should be described separately for each site. List the total net square feet of floor space to be renovated and the estimated cost per net sq. ft., excluding fixed equipment.

Additional Form Pages

Biographical Sketch Page - Provide a biographical sketch for all key personnel, strictly adhering to the two-page limitation for each.

Other Support Page - Provide the information requested for all key personnel.

Specific Instructions - Research Plan

The following instructions should be used in lieu of the PHS 398 instructions for this section of the application. The

Research Plan section of the application (Items 1-4) must strictly adhere to a limit of 25 pages. The outline suggested below should be followed in describing the program. All information critical to the review must be in the Research Plan, not in an appendix.

1. Specific Aims - Clearly present the aims of the animal resource improvement project and relate them to the short- and long-term goals of the institution's animal resource program.
2. Background and Significance - This section should address two areas: the overall animal care and use program and the significance of the proposed resource improvement project.

Background

Provide an overall description of the institution's animal care and use program. Provide relevant background information and describe the current status of the institution's animal resource facilities and program as they relate to biomedical research and research training. Describe the institution's overall involvement in animal-related research. This section should include a description of the following aspects of the animal resource:

- a. Administrative arrangements and structure of the animal resource. The lines of authority and responsibility for administering the institution's animal care and use program should be clearly presented. The role and composition of the IACUC and how compliance with relevant laws, policies, and guidelines is achieved should be included.
 - b. Animal care procedures and the animal health program. This section should describe housing, caging, feeding, record keeping, sanitation, and other animal care practices; animal health program which includes clinical services, laboratory support, preventive medicine programs, and any relevant specialized procedures; veterinary oversight; vendor surveillance; conditioning programs; colony and environmental monitoring; and diagnostic capabilities in anatomic pathology, clinical chemistry, hematology, and microbiology. Data should be provided to characterize the extent of these activities, such as numbers of laboratory procedures for monitoring animal health, veterinary inspections for animal health, etc. If specialized equipment items are requested, the husbandry program to utilize this equipment should be outlined.
 - c. Staffing. Outline the total staff and organization of the animal resource, both currently in place and as planned following the requested improvements. Briefly describe the qualifications of the animal care staff and the training opportunities available to them.
 - d. Animal Program Data. Indicate the number of animals (by species) used or produced per year and the average daily census (by species) for each facility. Provide a brief description of all on-campus and off-campus animal facilities, including sites where experimental surgery is performed. Indicate who manages each facility. Indicate whether the institution is AAALAC accredited. If equipment is requested for surgical or diagnostic facilities, the case load, species, types and numbers of surgeries or diagnostic tests must be documented.
 - e. Animal Program Funding. Provide, for the most recently completed Federal fiscal year (indicate year): (1) the institution's total annual PHS funding (direct costs) for research, both animal related and non-animal related; (2) the institution's total number and total direct costs of research projects using laboratory animals, indicating separately the number and costs of those funded from PHS and non-PHS sources; (3) for facilities for which improvement support is requested, list by facility name the number of research projects and total direct costs of the projects relevant to each.
- List all current financial support for the animal resource, including sources and amounts (e.g., recharge, core funding from the institution, etc.) and the annual operating budget (listed by major categories). Provide a copy of per diem and service charge schedules and indicate their method of determination (this information may be included in an Appendix).
- f. Previous and Future Improvements. Expenditures for capital improvements (facilities and equipment) during the past five years and future plans for meeting such needs should be described. Any previous support for improvement of the institution's animal facilities from the CMP, NCCR, NIH should be noted. The use of this support and its impact on the animal care program should be briefly described.
 - g. Program Needs. List deficiencies in the animal care program that have been cited by the American Association for Accreditation of Laboratory Animal Care (AAALAC), the Institutional Animal Care and Use Committee (IACUC) facility review reports, and the institution's PHS Animal Welfare Assurance Statement. Any problems in meeting the provisions of the Animal Welfare Act should also be addressed.

Significance

Describe the significance of the proposed resource improvement project to the institution's overall biomedical research programs, as well as to specific research projects that will be affected. If the resource will be used by a relatively small number of research projects, a brief description of those projects, including the source and amount of funding (direct costs) for the most recently completed Federal fiscal year should be indicated. If appropriate, the application should demonstrate both the need for the requested items and a sound plan for obtaining or maintaining the entire animal resource at required standards.

3. Progress Report/Preliminary Studies - Not applicable.

4. Research Design and Methods

Describe the improvement project and how the requested improvements will accomplish the goals described in the Specific Aims section above. It is important to describe how the requested improvements will correct the deficiencies and problems described in the Background section. Demonstrate how the proposed facility improvement program fits into the institution's overall plan to meet or maintain PHS standards for animal care and use. If the project is part of an overall (larger) facility improvement plan, the application should describe the larger plan and how the project fits into that plan.

Describe and provide detailed justifications for the requested equipment items. The manufacturer, model number, size, capacity, or design criteria, total unit cost and facility where it will be used should be included. Requests for surgical equipment must be justified by listing the number of investigators and PHS grant support received (can be provided in tabular form), the case load, and the types of surgical procedures performed. Failure to adequately justify each requested item will likely result in its deletion from the recommended budget.

For any proposed A&R, a narrative summary (as outlined below), line drawings, and cost estimates must be provided. The following format is suggested:

Narrative Summary

(1) Relate the proposed renovations to projected animal populations (by species) and research projects that will use the facility; (2) List the functional components, including the size (dimensions) and square footage of each component (room, alcove, cubicle, etc.) that will be directly affected by the renovation project; (3) List engineering criteria applicable to each component (mechanical, electrical, and utilities). Include information such as the number of air changes per hour, electrical power, light levels, hot and cold water, steam, etc.; (4) List appropriate architectural criteria, such as width of corridors and doors, surface finishes, etc.; (5) List all fixed equipment items requested for the renovated area; and (6) List all movable equipment items requested for the renovated area.

Line Drawings

(1) Submit line drawings on 8-1/2" x 11" paper only. (DO NOT SUBMIT BLUEPRINTS). These drawings will not be counted against the 25 page limit. All floor plans must be legible, with the scale clearly indicated.
(2) The line drawings of the proposed renovation must be at a scale adequate to explain the project. The drawings should indicate size (dimensions), function, and net and gross square feet of space for each room. The total net and gross square feet of space to be renovated should also be given.
(3) The plan should indicate the location of the proposed renovation area in the building.
(4) Include the as-built drawings of the proposed renovation area and indicate any areas which will be demolished.
(5) Changes or additions to existing mechanical and electrical systems should be clearly described in notes made directly on the plan or attached to the plan.
(6) Indicate the type(s) of new finishes to be applied to room surfaces.

Cost Estimates

Detailed cost estimates must be included.

Assurance to Provide Matching Funds

A letter of assurance to provide matching funds and the projected source of those funds, signed by the responsible institutional official, must be provided by the applicant prior to the time an award is made. If such a letter is not included with the application, the applicant must include a letter of intent, also signed by the appropriate institutional official, to provide the necessary matching funds.

The letter of assurance or the letter of intent should be placed as the final page of the application.

The completed original application (signed original including appendices, if any) and three exact photocopies of the signed application must be submitted to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892-4500**

At the time of submission, two additional copies of the application (with appendices, if any) must be sent under separate cover to:

Scientific Review Administrator
Comparative Medicine Review Committee
National Center for Research Resources
Westwood Building, Room 10A16
Bethesda, MD 20892-4500*

REVIEW CONSIDERATIONS

All applications will be reviewed for scientific and technical merit by an appropriate review committee managed by the Office of Review, NCCR. Second level review will be provided by the National Advisory Research Resources Council (NARRC). Review of the applications will be based on scientific merit, technical soundness, and cost effectiveness.

Factors considered in the appraisal of an animal resource improvement project include:

A. The Improvement Request

1. Need - The application should show how this grant support will help the institution meet or maintain standards of the Animal Welfare Act and PHS policies concerning the care and use of laboratory animals. The amount(s) and source(s) of funding for animal-related biomedical research which use the resource will be considered.

2. Scope of Institutional Planning - The institutional plan to assure a comprehensive and acceptable animal care and use program will be evaluated.

3. Budget - The budget will be evaluated in relationship to the application's responsiveness to these guidelines, justification provided for each of the requested items, cost effectiveness, and the institution's perceived commitment to the animal care program.

4. Animal Welfare - The extent to which the project will enhance the welfare of animals maintained in the facility to be improved will be evaluated. The benefit of the improvements to the welfare of animals in the facility, including advances in the humane treatment of the animals due to husbandry changes allowed by the improvements, will be assessed.

5. Design Considerations - The proposed project will be judged for technical soundness, appropriateness and suitability of the proposed renovation/project, and ability of the project to correct existing deficiencies.

B. The Animal Care Program

The scope of the animal care and use program to be enhanced by this facility improvement request should be carefully defined. For the purpose of this application, the animal care program should cover the entire applicant institution.

1. Animal Care - The quality of the animal husbandry program at the applicant institution will be assessed. The application should demonstrate that animals at all facilities of the institution will receive uniform, high-quality animal care.

2. Personnel - The technical and professional staff will be evaluated. The institution should have a sufficient number of professional staff with appropriate qualifications and experience to operate the animal resource in a competent manner. The facility should also have qualified non- professional staff and supporting services.

3. Administrative Arrangements - An evaluation will be made of the administrative arrangements for routine management of the animal resource. The institution should have a record of commitment and a sound plan for financial support of the resource, through a recharge system, per diem charges, institutional support, etc.

4. Resources and Environment - The suitability of the institutional setting for achieving the goals of the program will be considered. This will include an appraisal of the academic environment and the support for the animal resource by the administration and faculty.

AWARD CRITERIA

Applications will compete with all others in the G20 category for available funds. An institution must have current PHS funding for research involving laboratory animals to be eligible for an award. The following will also be considered when making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Institutional assurance of non-federal matching funds
- o Availability of funds

Evidence of continued PHS research funding will be verified prior to award.

Award Conditions

Following the actual award, funds for A&R will not be released until final architectural drawings, specifications, and updated cost estimates are approved by NCRR. No requests to initiate alterations or renovations will be entertained prior to receipt of the grant award from NIH and subsequent approval of working drawings and specifications by NIH staff. Renovations and equipment purchases must be initiated no later than twelve months after the start date of award. Awards will be made for one year and are not renewable.

INQUIRIES

Inquiries about the program may be directed to:

Director, Laboratory Animal Sciences Program
Comparative Medicine Program
National Center for Research Resources
Westwood Building, Room 857
Bethesda, MD 20892-4500
Telephone: (301) 594-7933
FAX: (301) 594-9149

Questions regarding fiscal matters are to be directed to:

Mr. Paul Karadbil
Office of Grants and Contracts Management
National Center for Research Resources
Westwood Building, Room 849
Bethesda, MD 20892-4500
Telephone: (301) 594-7955

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.306, Laboratory Animal Sciences and Primate Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78.410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NIH GUIDE, Volume 23, Number 27, July 22, 1994

PA NUMBER: PAR-94-084

P.T. 34; K.W. 1002002

National Center for Research Resources

Application Receipt Dates: October 1, February 1, June 1

PURPOSE

The National Center for Research Resources (NCRR) encourages the submission of individual animal resource improvement grant applications from small biomedical research institutions. The major objectives of this program are to upgrade animal facilities, develop administratively centralized programs of animal care, and enable institutions to comply with the USDA Animal Welfare Act and DHHS policies related to the care and use of laboratory animals. These awards do not require matching funds from the awardee institution. Support is limited to alterations and renovations (A&R) to improve laboratory animal facilities, and the purchase of major equipment items for animal resource, diagnostic laboratory, transgenic animal resources, or similar associated activities.

ELIGIBILITY REQUIREMENTS

Any domestic public or private institution, organization, or association is eligible to apply for this grant if it meets the following two requirements: (1) The institution must have one or more research projects supported by the PHS that involve the use of laboratory animals, and (2) The institution must have received less than \$1,500,000 (direct costs) of PHS support for research projects during the most recently completed Federal fiscal year.

Institutions and commercial firms providing only services or products and without a clearly defined animal related research component are not eligible to apply. Also, this program will not support requests for equipment used for teaching purposes and for housing non-research animals. Applications from other Federal agencies or institutions (e.g., Department of Veterans Affairs) are limited to requests for equipment only. Applicants may not submit more than one application or apply for other NCRR support for developing and improving institutional animal resources in the same Federal fiscal year.

For purposes of these guidelines, an "institution" is defined as the organizational component identified on page 1, item 14, of the form PHS 398 (rev. 9/91), for which descriptive information is provided on page 15 in the grant application form PHS 398 kit. Separate applications may be submitted from different colleges or schools on the same campus of a university within the same Federal fiscal year if they have different organizational component codes. If this is done, documentation from an appropriate institutional official, stating that the applications are part of a coordinated, campus-wide plan to improve the animal facilities, must be provided. The applicant institution is strongly encouraged to develop a single application for a campus-wide program with a single, centralized animal care program whenever possible or feasible.

MECHANISM OF SUPPORT

The mechanism available for the support of improvement projects is the Grant for Repair, Renovation, and Modernization of Existing Research Facilities (G20). The total budget request for the improvement grant application and award is limited to \$300,000 (direct costs), of which not more than \$200,000 may be used for alterations and renovations. Matching funds are not required. Because the nature and scope of the projects proposed in response to this PA may vary, it is anticipated that the size of an award will vary also.

Allowable Costs

Items that may be requested under this grant mechanism include:

- o A&R to improve existing laboratory animal facilities, and allowable fees associated with the A&R project
- o Major resource equipment related to the improvement project, such as animal cage systems and cage washers
- o Equipment items, or an aggregate of identical equipment items, that have a total cost of at least \$1,000. Items that are part of a system and require the purchase of small component parts (e.g., a rack and cages or microisolator units) may be requested and priced as a single item. A description of the individual components of such systems must be provided.
- o General purpose equipment items for centralized surgeries, diagnostic laboratories, transgenic animal facilities, and other similar associated activities when an integral part of the animal facility and available to all investigators
- o Basic diagnostic equipment (e.g., microscopes, centrifuges, refrigerators, etc.) to be used in support of the animal facility, but not for research
- o Environmental monitoring systems. However, if such a system has multiple uses (e.g., the monitoring of research data or security), only those costs related to monitoring or providing for animal care (e.g., environmental monitoring) are allowable

Improvement grants are not intended to provide support for:

- o General operational support for the resource (e.g., funding for personnel, consumable supplies for routine animal care, or small equipment items)
- o Specialized research equipment or facilities for use by only a few investigators
- o New construction, including the completion of shell space
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- o Office and research equipment, computers or data processing items
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RESEARCH OBJECTIVES

Animal resource improvement grants are awarded to assist biomedical research institutions in upgrading animal facilities and developing administratively centralized and uniformly effective programs of research animal care. Another major objective is to assist institutions in complying, and maintaining compliance, with provisions of the Animal Welfare Act and PHS policies related to the care and use of laboratory animals.

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Applications must follow the instructions provided in the form PHS 398 kit, except for the following:

Form Page 1:

Item 2a - Check the box marked "YES" and type in the number and title of the program announcement.

Item 2b - Insert "G20"

Item 5 - Check the box marked "No" at Item 5a. Item 5b - Not applicable.

Form Page 2:

Personnel - Only key personnel should be listed here even though salary support is not requested. This must include the chief or consulting veterinarian.

Form Page 4: Detailed Budget for Initial Budget Period

Personnel Category - List only key individuals; salary support should not be requested.

The total cost of the equipment and A&R needed should be entered in the rectangular space under the appropriate headings on the left. Equipment should be classified as movable or fixed, using the institution's own classification guidelines. Fixed equipment is considered as part of the A&R request. The right hand column should reflect only the PHS request. The Total Direct Costs (bottom right hand column total) should be the total request to the PHS. The total request for PHS support may not exceed \$300,000. Of this total, the A&R request may not exceed \$200,000.

Form Page 5 - Budget for Entire Proposed Project Period - Not applicable (do not complete this section).

A cost estimate should be provided, and placed between Form Page 4. This estimate should detail:

1. For movable equipment, the dollar request from NIH, amount to be funded from other sources, and total cost.
 2. For eligible A&R costs, the dollar request from NIH, amount to be funded from other sources, and total cost.
 3. For total project cost, the dollar request from NIH, amount to be funded from other sources, and total cost.
- For funding from other sources, please indicate the source(s).

For alterations and renovations requests, list separately the projected costs of: (a) Demolition; (b) General; (c) Plumbing; (d) HVAC; (e) Electrical; (f) Architect/Engineer Fee; (g) Other Costs (Specify); and (h) Fixed Equipment, with the total eligible A&R costs listed. If multiple sites are involved, the A&R and cost estimates should be described separately for each site. List the total net square feet of floor space to be renovated and the estimated cost per net sq. ft., excluding fixed equipment.

Additional Form Pages

Biographical Sketch Page - Provide a biographical sketch for all key personnel, strictly adhering to the 2 page limitation for each.

Other Support Page - Provide the information requested for all key personnel.

Specific Instructions - Research Plan

The following instructions should be used in lieu of the PHS 398 instructions for this section of the application. The Research Plan section of the application (Items 1-4) must strictly adhere to a limit of 25 pages. The outline suggested below should be followed in describing the program. All information critical to the review must be in the Research Plan, not in an appendix.

1. Specific Aims - Clearly present the aims of the animal resource improvement project and relate them to the short- and long-term goals of the institution's animal resource program.

2. Background and Significance - This section should address two areas: the overall animal care and use program and the significance of the proposed resource improvement project.

Background

Provide an overall description of the institution's animal care and use program. Provide relevant background information and describe the current status of the institution's animal resource facilities and program as they relate to biomedical research and research training. Describe the institution's overall involvement in animal-related research. This section should include a description of the following aspects of the animal resource:

a. Administrative arrangements and structure of the animal resource. The lines of authority and responsibility for administering the institution's animal care and use program should be clearly presented. The role and composition of the IACUC and how compliance with relevant laws, policies, and guidelines is achieved should be included.

b. Animal care procedures and the animal health program. This section should describe housing, caging, feeding, record keeping, sanitation, and other animal care practices; animal health program which includes clinical services, laboratory support, preventive medicine programs, and any relevant specialized procedures; veterinary oversight; vendor surveillance; conditioning programs; colony and environmental monitoring; and diagnostic capabilities in anatomic pathology, clinical chemistry, hematology, and microbiology. Data should be provided to characterize the extent of these activities, such as numbers of laboratory procedures for monitoring animal health, veterinary inspections for animal health, etc. If specialized equipment items are requested, the husbandry program to utilize this equipment should be outlined.

c. Staffing. Outline the total staff and organization of the animal resource, both currently in place and as planned following the requested improvements. Briefly describe the qualifications of the animal care staff and the training opportunities available to them.

d. Animal Program Data. Indicate the number of animals (by species) used or produced per year and the average daily census (by species) for each facility. Provide a brief description of all on-campus and off-campus animal facilities, including sites where experimental surgery is performed. Indicate who manages each facility. Indicate whether the institution is AAALAC accredited. If equipment is requested for surgical or diagnostic facilities, the case load, species, types and numbers of surgeries or diagnostic tests must be documented.

e. Animal Program Funding. Provide, for the most recently completed Federal fiscal year (indicate year): (1) the institution's total annual PHS funding (direct costs) for research, both animal related and non-animal related; (2) the institution's total number and total direct costs of research projects using laboratory animals, indicating separately the number and costs of those funded from PHS and non-PHS sources; (3) for facilities for which improvement support is requested, list by facility name the number of research projects and total direct costs of the projects relevant to each.

List all current financial support for the animal resource, including sources and amounts (e.g., recharge, core funding from the institution, etc.) and the annual operating budget (listed by major categories). Provide a copy of per diem and service charge schedules and indicate their method of determination (this information may be included in an Appendix).

f. Previous and Future Improvements. Expenditures for capital improvements (facilities and equipment) during the past five years and future plans for meeting such needs should be described. Any previous support for improvement of the institution's animal facilities from the CMP, NCCR, NIH should be noted. The use of this support and its impact on the animal care program should be briefly described.

g. Program Needs. List deficiencies in the animal care program which have been cited by the American Association for Accreditation of Laboratory Animal Care (AAALAC), the Institutional Animal Care and Use Committee (IACUC) facility review reports, and the institution's PHS Animal Welfare Assurance Statement. Any problems in meeting the provisions of the Animal Welfare Act should also be addressed.

Significance

Describe the significance of the proposed resource improvement project to the institution's overall biomedical research programs, as well as to specific research projects that will be affected. If the resource will be used by a relatively small number of research projects, a brief description of those projects, including the source and amount of funding (direct costs) for the most recently completed Federal fiscal year should be indicated. If appropriate, the application should demonstrate both the need for the requested items and a sound plan for obtaining or maintaining the entire animal resource at required standards.

3. Progress Report/Preliminary Studies - Not applicable.

4. Research Design and Methods

Describe the improvement project and how the requested improvements will accomplish the goals described in the Specific Aims section above. It is important to describe how the requested improvements will correct the deficiencies and problems described in the Background section. Demonstrate how the proposed facility improvement program fits into the institution's overall plan to meet or maintain PHS standards for animal care and use. If the project is part of an overall (larger) facility improvement plan, the application should describe the larger plan and how the project fits into that plan.

Describe and provide detailed justifications for the requested equipment items. The manufacturer, model number, size, capacity, or design criteria, total unit cost and facility where it will be used should be included. Requests for surgical equipment must be justified by listing the number of investigators and PHS grant support received (can be provided in tabular form), the case load, and the types of surgical procedures performed. Failure to adequately justify each requested item will likely result in its deletion from the recommended budget.

For any proposed A&R, a narrative summary (as outlined below), line drawings, and cost estimates must be provided. The following format is suggested:

Narrative Summary

(1) Relate the proposed renovations to projected animal populations (by species) and research projects that will use the facility; (2) List the functional components, including the size (dimensions) and square footage of each component (room, alcove, cubicle, etc.) that will be directly affected by the renovation project; (3) List engineering criteria applicable to each component (mechanical, electrical, and utilities). Include information such as the number of air changes per hour, electrical power, light levels, hot and cold water, steam, etc.; (4) List appropriate architectural criteria, such as width of corridors and doors, surface finishes, etc.; (5) List all fixed equipment items requested for the renovated area; and (6) List all movable equipment items requested for the renovated area.

Line Drawings

(1) Submit line drawings on 8-1/2" x 11" paper only. (DO NOT SUBMIT BLUEPRINTS). These drawings will not be counted against the 25 page limit. All floor plans must be legible, with the scale clearly indicated.

(2) The line drawings of the proposed renovation must be at a scale adequate to explain the project. The drawings should indicate size (dimensions), function, and net and gross square feet of space for each room. The total net and gross square feet of space to be renovated should also be given.

(3) The plan should indicate the location of the proposed renovation area in the building.

(4) Include the as-built drawings of the proposed renovation area and indicate any areas which will be demolished.

(5) Changes or additions to existing mechanical and electrical systems should be clearly described in notes made directly on the plan or attached to the plan.

(6) Indicate the type(s) of new finishes to be applied to room surfaces.

Cost Estimates

Detailed cost estimates must be included.

The completed original application (signed original including appendices, if any) and three exact photocopies of the signed application must be submitted to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892-4500*

At the time of submission, two additional copies of the application (with appendices, if any) must be sent under separate cover to:

Scientific Review Administrator
Comparative Medicine Review Committee
National Center for Research Resources
Westwood Building, Room 10A16
Bethesda, MD 20892-4500*

REVIEW CONSIDERATIONS

All applications will be reviewed for scientific and technical merit by an appropriate review committee managed by the Office of Review, NCRR. Second level review will be provided by the National Advisory Research Resources Council (NARRC). Review of the applications will be based on scientific merit, technical soundness, and cost effectiveness.

Factors considered in the appraisal of an animal resource improvement project include:

A. The Improvement Request

1. Need - The application should show how this grant support will help the institution meet or maintain standards of the Animal Welfare Act and PHS policies concerning the care and use of laboratory animals. The amount(s) and source(s) of funding for animal-related biomedical research which use the resource will be considered.

2. Scope of Institutional Planning - The institutional plan to assure a comprehensive and acceptable animal care and use program will be evaluated.

3. Budget - The budget will be evaluated in relationship to the application's responsiveness to these guidelines, justification provided for each of the requested items, cost effectiveness, and the institution's perceived commitment to the animal care program.

4. Animal Welfare - The extent to which the project will enhance the welfare of animals maintained in the facility to be improved will be evaluated. The benefit of the improvements to the welfare of animals in the facility, including advances in the humane treatment of the animals due to husbandry changes allowed by the improvements, will be assessed.

5. Design Considerations - The proposed project will be judged for technical soundness, appropriateness and suitability of the proposed renovation/project, and ability of the project to correct existing deficiencies.

B. The Animal Care Program

The scope of the animal care and use program to be enhanced by this facility improvement request should be carefully defined. For the purpose of this application, the animal care program should cover the entire applicant institution.

1. Animal Care - The quality of the animal husbandry program at the applicant institution will be assessed. The application should demonstrate that animals at all facilities of the institution will receive uniform, high-quality animal care.

2. Personnel - The technical and professional staff will be evaluated. The institution should have a sufficient number of professional staff with appropriate qualifications and experience to operate the animal resource in a competent manner. The facility should also have qualified non-professional staff and supporting services.

3. Administrative Arrangements - An evaluation will be made of the administrative arrangements for routine management of the animal resource. The institution should have a record of commitment and a sound plan for financial support of the resource, through a recharge system, per diem charges, institutional support, etc.

4. Resources and Environment - The suitability of the institutional setting for achieving the goals of the program will be considered. This will include an appraisal of the academic environment and the support for the animal resource by the administration and faculty.

AWARD CRITERIA

Applications will compete with all others in the G20 category for available funds. An institution must have current PHS funding for research involving laboratory animals to be eligible for an award. The following will also be considered when making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds

Evidence of continued PHS research funding will be verified prior to award.

Award Conditions

Following the actual award, funds for A&R will not be released until final architectural drawings, specifications, and updated cost estimates are approved by NCRR. No requests to initiate alterations or renovations will be entertained prior to receipt of the grant award from NIH and subsequent approval of working drawings and specifications by NIH staff. Renovations and equipment purchases must be initiated no later than twelve months after the start date of award. Awards will be made for one year and are not renewable.

INQUIRIES

Inquiries about the program are to be directed to:

Director, Laboratory Animal Sciences Program
Comparative Medicine Program
National Center for Research Resources
Westwood Building, Room 857
Bethesda, MD 20892-4500
Telephone: (301) 594-7933

Questions regarding fiscal matters are to be directed to:

Mr. Paul Karadbil
Office of Grants and Contracts Management
National Center for Research Resources
Westwood Building, Room 849
Bethesda, MD 20892-4500
Telephone: (301) 594-7955

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.306, Laboratory Animal Sciences and Primate Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78.410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NATIONAL RESEARCH SERVICE AWARDS INSTITUTIONAL TRAINING GRANTS IN GENOMIC SCIENCE

NIH GUIDE, Volume 23, Number 27, July 22, 1994

PA NUMBER: PA-94-085

P.T. 22; K.W. 0720005, 1215018

National Center for Human Genome Research

PURPOSE

[This is a reissue of a Program Announcement that appeared in the NIH Guide for Grants and Contracts, Vol. 20, No. 46, December 3, 1991.]

The National Center for Human Genome Research (NCHGR) announces the availability of support for institutional training programs in genomic sciences to train scientists with multi-disciplinary skills that will allow them to engage in research that will accomplish the goals of the Human Genome Program (HGP) and to take full advantage of the resulting genomic data and resources to solve biomedical problems and increase our understanding of human biology. These research training opportunities will be supported through institutional training grants, which may support pre-doctoral, postdoctoral, and short-term trainees. The genomic sciences multidisciplinary training program is intended to expand the research capabilities of individuals with backgrounds in either molecular biology or a non-biological scientific discipline relevant to genomic sciences (e.g., physical, chemical, mathematical, computer, and/or engineering sciences). Short-term training opportunities are intended for students in non-biological scientific disciplines who wish to learn more about genomic sciences.

The NCHGR wishes to expand the number of institutions capable of training scientists in genomic sciences and strongly encourages institutions with academically outstanding departments in molecular biology and one or more of the non-biological scientific disciplines relevant to genomic sciences to consider developing training programs that would be responsive to the needs of the HGP.

ELIGIBILITY REQUIREMENTS

Only domestic universities and medical colleges may apply for training grants supported under the National Research Service Award (NRSA) mechanism. Only U.S. citizens, non-citizen nationals, or permanent residents of the United States may be appointed as trainees on NRSA-funded training grants.

MECHANISM OF SUPPORT

Support for this program will be through the National Research Service Award (T32) Program. Institutional training grants are made for project periods of up to five years and are renewable.

RESEARCH OBJECTIVES

Background

The National Institutes of Health (NIH) is currently engaged, along with several other federal, private, and international organizations, in a 15-year research program designed to characterize the human genome and the genomes of selected model organisms. The HGP has the following interrelated goals: the construction of high-resolution genetic linkage maps, the development of detailed physical maps, and the determination of the complete nucleotide sequence of the human genome and the genomes of selected organisms; the development of efficient methods of identifying genes and for placement of known genes on physical maps or sequenced DNA; the development of the capability to collect, store, distribute and analyze the data and materials produced; the development of new technologies to achieve these goals; and the identification of major issues related to the ethical, legal and social implications (ELSI) of genome research, and the development of policy options to address them. The products of the HGP will include information and material resources, as well as new technologies, that will be available to the entire research community to facilitate further research leading to the prevention, diagnosis, and therapy of disease, as well as to further understanding of human biology.

In 1990, the NCHGR and the Department of Energy (DOE) jointly published a plan that set out specific goals to be achieved in the first five-year phase of the U.S. human genome program. Anticipating the attainment of much of the initial set of goals, the NCHGR and DOE recently extended the original goals of the Human Genome Program. These goals are described in the article, "A New Five-Year Plan for the U.S. Human Genome Project," (Science, Vol. 262, pp. 43-46, October 1, 1993) and cover the years 1994-1998.

The HGP is opening up new approaches to biomedical problems. Attaining the solutions to these problems will require that the research methods of the biological sciences be augmented and complemented by the approaches and methods of non-biological scientific disciplines. There is a critical shortage of scientists with the appropriate complementary skills to bring such multidisciplinary approaches to genomic research. Individuals capable of developing new technology and tools are needed, as are molecular biologists capable of taking multi-disciplinary approaches and using the resources provided by the HGP to address important biomedical and biological research problems. The intent of the NCHGR's research training program is to fill this need. Successful training programs will attract individuals with backgrounds in relevant non-biological scientific disciplines or molecular biology and should have sufficient flexibility to provide the appropriate interdisciplinary training to individual candidates. It is essential that trainees who are supported under this program receive thorough training in multi-disciplinary approaches to modern biomedical research.

Training Program

Genomic science represents a new scientific approach to solving biomedical research problems. Thus, most institutions have not, as yet, developed graduate and post-graduate training programs in genomic science that would enroll students or postdoctoral fellows trained in molecular biology or one of the non-biological scientific disciplines appropriate for genomic science and provide training that would allow them to develop complementary expertise in another discipline. Because of the unique training requirements of the HGP, the NCHGR recognizes that institutions will need to develop new training programs. Therefore, the NCHGR strongly encourages applications from institutions that can demonstrate academic excellence in molecular biology and one or more of the non-biological scientific disciplines appropriate for genomic science, have outstanding faculties that are committed and willing to cooperate in developing a genomic sciences training program, have access to a pool of highly qualified graduate students and postdoctoral fellows, and have sound training plans, but have not as yet established training programs in genomic science. Applications from institutions that wish to apply as a consortium are welcomed, but must demonstrate that they can mount a well-coordinated and integrated program.

Format. The NCHGR is seeking to support training programs that allow trainees access to broad research opportunities across disciplinary and departmental lines, while not sacrificing the standards of depth and creativity characteristic of the best doctoral and postdoctoral programs of individual departments. The NCHGR recognizes that there is no one model for this type of training and encourages institutions to develop innovative training programs that are responsive to the needs of genomic sciences as well as to the needs of individual trainees.

Types of Training Positions Allowed. An institutional training grant may include all of the following types of training positions:

1. Predoctoral positions--for students with undergraduate degrees in chemistry, physics, mathematics, computer sciences or engineering sciences who wish to pursue training in molecular biology or for individuals with undergraduate degrees in a biological science who wish to pursue an interdisciplinary doctoral degree that incorporates one or more of the non-biological disciplines mentioned above. An exposure to technology development is encouraged for all predoctoral trainees.
2. Postdoctoral positions--for postdoctoral students trained in chemistry, physics, mathematics, computer sciences, or engineering sciences who wish to pursue additional training in molecular biology or for individuals with training in molecular biology who wish to pursue an area of technology development as it relates to genomic science.
3. Short-term training positions--only for undergraduate or graduate students trained in chemistry, physics, mathematics, computer sciences or engineering sciences who wish to spend three to six months in a molecular biology

laboratory in order to get acquainted with the field.

The number of postdoctoral positions should be limited to approximately one-third of the total full-time training positions. No application that requests only postdoctoral positions will be accepted.

Stipends and Other Allowable Costs. The stipends for predoctoral and postdoctoral trainees are at the new level, which was announced in the NIH Guide for Grants and Contracts, Vol. 23, No. 10, March 11, 1994. Full tuition may be requested for full-time predoctoral trainees only. Institutional costs of up to \$1,500 per year per predoctoral trainee and up to \$2,500 per year per postdoctoral trainee may be requested to defray the costs of other training-related expenses, such as staff salaries, consultant costs, equipment, research supplies, and travel. The institution may receive up to \$125 per month to offset the cost of tuition, fees, travel, supplies, and other expenses for each short-term research training position. Indirect cost allowance based on eight percent of total allowable direct costs exclusive of tuition, fees, health insurance, and expenditures for equipment, or actual indirect costs, whichever is less, may be requested.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). Submission dates for new and competing applications are January 10, May 10, and September 10, annually. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. The title and number of this program announcement must be typed in Item 2a on the face page of the application.

The completed original application and five legible copies must be delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Postdoctoral trainees and fellows supported under the National Research Service Award Program may be subject to payback provisions. Details about the policies and payback provisions governing payback requirements were published in the NIH Guide for Grants and Contracts, Vol. 22, No. 27, July 30, 1993.

REVIEW CONSIDERATIONS

Applications submitted in response to this program announcement will be reviewed in accordance with the usual NIH peer review procedures. The following review criteria will be applied: the research and training experience and leadership capabilities of the program director; the qualifications and commitment of the training faculty as measured by research grant support, publication record, and past training record; the quality of the applicant pool; the number of predoctoral students currently receiving training; the design of the training program including, for applications assigned to the NCHGR, its relevance to the goals of the Human Genome Program; provisions for guidance and quality control of the individual trainee's programs; and adequacy of the resources and environment. For institutions that are in the process of developing a genomic science training program, greater weight will be given to the design of the institution's training program. For institutions that are submitting competing renewals, greater weight will be given to both the past performance of the training program and the future directions of the training program. Following assessment of the quality of the proposed training program and assignment of priority scores indicative of the merit, the initial review group will evaluate each application on its (1) plans for attracting and retaining individuals from underrepresented minority groups and (2) plans for instructing trainees in the responsible conduct of research. If an application is deficient in one of these areas, it may not be funded, regardless of scientific merit. Site visits will not be conducted as part of the review process, except in unusual circumstances. Therefore, applicants must present a complete and well-justified written application and not depend on a site visit to amplify the application.

Subsequent to the initial review, applications will be reviewed by the appropriate National Advisory Council. Among the information the Council will consider in addition to the merit of the training program is the initial review group's comments on plans for, or experience in, the recruitment and retention of individuals from underrepresented minority groups into the training program.

AWARD CRITERIA

For applications assigned to the National Center for Human Genome Research, the following criteria will be used in making funding decisions: quality of the training program as determined by its potential to meet the short- and long-term goals of the HGP; leadership capabilities of the program director and the quality of the participating faculty; commitment of the biology and non-biology faculty to the training program; and availability of funds. The NCHGR understands that it takes time for institutions to develop cooperative efforts across departmental and scientific discipline lines and this factor will also be considered when funding decisions are made.

INQUIRIES

Written, telephone, and e-mail inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Bettie J. Graham, Ph.D.
Mapping Technology Branch
National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531
E-mail: Bettie_Graham@ocshost.nlm.nih.gov

For information about PHS grants policy, applicants may contact:

Ms. Jean Cahill
Grants and Contracts Management Branch
National Center for Human Genome Research
Building 38A, Room 613
Bethesda, MD 20892
Telephone: (301) 402-0733
E-mail: Jean_Cahill@occhost.nlm.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.172. Awards are made under the authority of the Section 487, Public Health Service Act as amended (42 USC 288) and administered under PHS Grants Policies and Title 42 of the Code of Federal Regulations, Part 66. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

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Bethesda, MD 20816***



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For Grants and Contracts

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Vol. 23, No. 28
July 29, 1994

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NOTICES

SUPPORT OF SCIENTIFIC COURSES

NIH GUIDE, Volume 23, Number 28, July 29, 1994

P.T. 34; K.W. 1014006

National Institute of General Medical Sciences

This announcement updates the policy of the National Institute of General Medical Sciences (NIGMS) regarding the support of scientific courses through the conference grant (R13) mechanism. Applicants planning to submit investigator-initiated conference grant applications for scientific courses are advised that it is important that they contact NIGMS program staff for guidance in the areas appropriate for the NIGMS and the preparation of the application itself. Applications received without prior contact may be delayed in the review process or returned to the applicant without review.

INQUIRIES

For further information, contact:

Dr. Michael R. Martin
Deputy Associate Director for Program Activities
National Institute of General Medical Sciences
Westwood Building, Room 936
45 Center Drive, MSC 6200
Bethesda, MD 20892-6200
Telephone: (301) 594-7753

NOTICES OF AVAILABILITY (RFPs AND RFAs)

AVAILABILITY OF SITE TO CONDUCT A LARGE SCALE EFFICACY TRIAL OF CANDIDATE PNEUMOCOCCAL VACCINES IN A LESS DEVELOPED COUNTRY

NIH GUIDE, Volume 23, Number 28, July 29, 1994

SOURCES SOUGHT ANNOUNCEMENT

P.T. 34; K.W. 0740075, 1002003

National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID), Division of Microbiology and Infectious Diseases (DMID), is seeking sources in developing countries that are capable of conducting one or more randomized, controlled, double-blind field trials to demonstrate the protective efficacy of new candidate pneumococcal vaccines against vaccine-type pneumococcal infections in an infant population.

A pneumococcal vaccine containing capsular polysaccharide antigens of 23 serotypes is currently available and used in adults and high risk children over two years of age. Unfortunately, the vaccine is poorly immunogenic in children below the age of two years and in other high-risk groups. To enhance the immunogenicity in these latter populations, capsular polysaccharides have been coupled to carrier proteins to form conjugate vaccines similar to the Hib conjugate vaccines recently licensed and now part of the routine infant vaccination schedule in many countries worldwide.

Because *Streptococcus pneumoniae* is a primary etiological agent of pneumonia and contributes significantly to the development of bacteremia and sepsis among young children in developing countries, it is very important to test the safety and efficacy of these new candidate pneumococcal vaccines in this setting. In selecting a site, it will be

essential that information be available on the epidemiology of pneumococcal disease especially with regard to the etiology of pneumonia in young children in addition to knowledge of the individual serotypes causing disease among children with invasive infections. Other important factors that will be considered in the site selection process include: (1) availability of a population from a developing or intermediate country that is sufficiently large and stable to facilitate enrollment and follow-up; (2) an existing EPI program with a coverage greater than 75 percent; (3) the ability to demonstrate that a sufficient number of cases of confirmed pneumococcal infection can be detected to meet trial requirements; (4) an existing laboratory infrastructure to conduct serologic assays and perform definitive diagnostic tests for pneumonia; (5) the ability to collect both acute and convalescent serum specimens from suspected cases; (6) the ability to collect and store sterile site specimens and biological specimens, including nasopharyngeal aspirates, before and after immunization and during and after disease; (7) the capability to recruit a sufficient number of infants to have a high probability that the lower limit of a two-sided 95 percent confidence interval for absolute efficacy to prevent pneumococcal bacteremia with a new pneumococcal candidate vaccine compared to a control vaccine will be greater than 40 percent if true VE is 80 percent. The sample size should also take into consideration drop-out rates and other local factors that might affect the overall calculations; (8) efforts to ensure that the quality of the data for use by vaccine manufacturers when submitting applications for licensure will meet the standards established by the FDA; (9) an adequate morbidity and mortality surveillance mechanism in place; (10) good access to medical care and treatment; (11) the ability to randomize by individual and ensure the vaccine assignment of those enrolled; and (12) the ability to maintain surveillance for a period of up to two years.

The proposed study will represent a joint collaborative effort among the NIH, NIAID, the WHO, and USAID. The purpose of this advertisement is to determine if there are sources capable of conducting efficacy trials with the primary emphasis on assessing the absolute efficacy of new candidate pneumococcal vaccines compared to a control vaccine in preventing invasive pneumococcal infections in infants. Secondary aims might include examining the general safety of the vaccine under investigation, exploring serological correlates of protection among immunized infants, and determining the effect of the vaccine on nasopharyngeal colonization and overall mortality.

Interested parties should submit six copies of a capability statement no later than September 30, 1994. The statement should, at a minimum, address each of the areas outlined above.

This Sources Sought Announcement is a request for information to assist the NIAID in planning for future efficacy trials. It may or may not result in a solicitation; at this time, no funds are available for these purposes.

INQUIRIES

Interested parties are encouraged to respond by September 30, 1994. Respondents are invited to discuss additional terms or conditions with NIAID by contacting:

David L. Klein, Ph.D.
Division of Microbiology & Infectious Diseases
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3803
6003 Executive Boulevard, MSC 7630
Bethesda, MD 20892-7630
Telephone: (301) 496-5305
FAX: (301) 496-8030

VACCINE AVAILABILITY

NIH GUIDE, Volume 23, Number 28, July 29, 1994

SOURCES SOUGHT ANNOUNCEMENT

P.T. 34; K.W. 0740075, 1002003

National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID) is soliciting the interest of manufacturers of pneumococcal conjugate vaccines or other new candidate pneumococcal vaccines to have their products considered for use in Phase II and Phase III clinical trials in developing and intermediate countries. Although sources of pneumococcal vaccine are sought, no contract will result from this announcement.

To be considered, conjugate vaccines must be multivalent and contain the following serotypes: 1, 5, 6B, 14, 19F, and 23F in addition to 9V and/or 18C. Data must be available demonstrating successful Phase I clinical trials in infants with an experimental lot of vaccine containing at least four of the above serotypes in addition to information that the vaccine meets U.S. FDA licensing requirements. Quantities of vaccine sufficient to conduct a large scale Phase III trial must also be made available by June 1995 without cost to the government. Manufacturers are required to provide information on basic manufacturing methods and the total content of the candidate pneumococcal vaccines including the type of adjuvant and preservative used, the type of carrier protein, and the chemical constructs.

Selected products will be evaluated for safety and immunogenicity in a pre-determined Phase III trial site in addition to several of NIAID's contracted Vaccine Evaluation and Treatment Units. If more than one product is under consideration, the products will be compared to each other for safety and immunogenicity to facilitate the selection of a vaccine for eventual use in the field trial. The NIAID plans to cross-reference the manufacturer's Investigational New Drug (IND) exemption application or Master File for information to support studies submitted under NIAID's IND.

INQUIRIES

Interested parties are encouraged to respond by September 30, 1994. Respondents are invited to discuss additional terms or conditions with NIAID by contacting:

David L. Klein, Ph.D.
Division of Microbiology & Infectious Diseases
National Institute of Allergy & Infectious Diseases
Solar Building, Room 3B03
6003 Executive Boulevard, MSC 7630
Bethesda, MD 20892-7630
Telephone: (301) 496-5305
FAX: (301) 496-8030

MONITOR AND MAINTAIN PHARMACY RESIDENCY PROGRAM OF THE CLINICAL CENTER

NIH GUIDE, Volume 23, Number 28, July 29, 1994

RFP AVAILABLE: OPC-CC-94-23

P.T. 34; K.W. 0710130

Warren Grant Magnuson Clinical Center

The Warren Grant Magnuson Clinical Center, National Institutes of Health, has a requirement for an academic institution located within two and one-half hours travel time from the Washington, DC metropolitan area, which offers a pharmacy degree program to monitor and maintain the current Pharmacy Residency Program. The academic institution must be formally accredited by the American Council on Pharmaceutical Education.

The program currently includes the pharmacy practice residency and three specialized residencies: (1) Oncology pharmacy practice, (2) primary care pharmacy practice, and (3) drug information and pharmacotherapy. Pharmacy practice residents rotate among the following areas: acute care in oncology and internal medicine, ambulatory care, pharmaceutical development, drug information and pharmacotherapy, and pharmacy management. Elective rotations are also offered in pediatric oncology, mental health, critical care medicine and pharmacokinetics. Off-site rotations at nearby organizations, such as the Food and Drug Administration (FDA), and U.S. Pharmacopoeia Convention are also available.

In addition to a regular 40-hour week, residents will be required to work every other weekend (two eight-hour shifts) and an eight-hour shift on five federal holidays. The period of performance will be for one year with four 12-month option periods. This will be a five-year contract.

The contractor shall be required to provide the services of a pharmacy resident each year of the contract in the following four categories: (1) General Hospital Pharmacy Practice, (2) Primary Care, (3) Oncology Pharmacy Practice, and (4) Drug Information and Pharmacotherapy. Each year, the contractor will develop a mechanism to provide a list of qualified candidates to fill each of the four residency positions. The residents will be replaced yearly by the contractor upon completion of the training goals and objectives that have been prepared for each program. Additionally, the contractor shall be required to review and evaluate the residency training goals and objectives, qualifications of the Pharmacy Department preceptors, and training sites and provide recommendations on how to improve and/or expand the existing programs.

INQUIRIES

This Request for Proposals (RFP) will be issued on or about August 1, 1994, with the estimated proposal due by September 15, 1994. All sources who consider themselves qualified are encouraged to submit proposals. Telephone requests for copies of the solicitation or other requests for information are not acceptable and will not be honored. All written requests must cite the RFP number and include two self-addressed mailing labels. Requests for copies of the solicitation are must be directed to:

Mrs. Johnnie L. Rice
ATTN: RFP-CC-94-23
Office of Purchasing and Contracts
Warren Grant Magnuson Clinical Center
6010 Executive Boulevard, Room 216
Bethesda, MD 20892

LEPROSY RESEARCH SUPPORT AND MAINTENANCE OF AN ARMADILLO COLONY

NIH GUIDE, Volume 23, Number 28, July 29, 1994

RFP AVAILABLE: NIH-NIAID-DMID-95-07

P.T. 34; K.W. 1002002

National Institute of Allergy and Infectious Diseases

The Division of Microbiology and Infectious Diseases (DMID) of the National Institute of Allergy and Infectious Diseases (NIAID) is soliciting proposals from investigators who have the capability and facilities to separate *M. leprae* bacilli from infected armadillo tissues, devise an analytical method(s) for the determination of the profile of *M. leprae* surface antigens to be employed in biological test systems, establish and maintain an armadillo colony of the nine-banded species (*Dasypus novemcinctus*), propagate *M. leprae* in the armadillos, monitor the colony and determine when an armadillo is highly infected with *M. leprae*, and aseptically harvest the infected tissues from the armadillos. These purified antigens and other cell products will be distributed to researchers at the direction of this institute.

Request for Proposals (RFP) NIH-NIAID-DMID-95-07 will be available on or about August 1, 1994. Responses are due by close of business on October 17, 1994. It is estimated that one contract for Parts I and II together, or two separate contracts for Parts I and II separately will be awarded incrementally for a period of seven years. Any responsible offeror may submit a proposal that will be considered by the Government.

INQUIRIES

To receive a copy of this RFP, supply this office with a self-addressed mailing label. Telephone inquiries will not be honored and all inquiries must be in writing and addressed to:

Contracting Officer
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3C07
6003 Executive Boulevard
Bethesda, MD 20892

This advertisement does not commit the Government to award a contract.

GENETIC ANALYSIS OF BIPOLAR DISORDER AND SCHIZOPHRENIA

NIH GUIDE, Volume 23, Number 28, July 29, 1994

RFA AVAILABLE: MH-94-010

P.T. 34; K.W. 0715177, 1002019, 1002058, 0785055

National Institute of Mental Health

Application Receipt Date: October 19, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Mental Health (NIMH) is soliciting applications to use the resources and experience of funded investigators of the Institute's "Diagnostic Centers for Psychiatric Linkage Studies" to complete the objectives outlined in the original RFA for this program (RFA: MH-89-05), and to move to the second phase of study of the genetics of bipolar disorder and schizophrenia: genotyping and genetic analysis of material from subjects ascertained during the data collection phase of this study. Combining expertise in the areas of diagnosis, genetic epidemiology, biostatistics, and molecular genetics should make it possible to identify those genetic factors which have a significant impact on the expression of these disorders. The applicants are expected to use data from the families ascertained and assessed by the Diagnostic Centers.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Genetic Analysis of Bipolar Disorder and Schizophrenia, is related to the priority area of mental disorders in adults. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Only currently funded bipolar disorder or schizophrenia Diagnostic Centers for Psychiatric Linkage Studies are eligible to apply for up to three years of support. The six currently active Diagnostic Centers for Psychiatric Linkage Studies are considered uniquely structured to undertake this study for several reasons: their use of a common protocol for data collection that has included uniform assessments and extension rules permitting pooling of data across sites; their

ability to follow subjects longitudinally and track changes in diagnoses or compare diagnoses; and their existing infrastructure, scope and aims, and multidisciplinary staffing.

MECHANISM OF SUPPORT

Awards will be made as cooperative agreements (U01). In cooperative agreements, unlike traditional research grants, substantial NIMH programmatic involvement with the recipient is anticipated during the performance of the planned activity. It is expected that up to \$250,000 in direct costs for each cooperative agreement study site will be available in fiscal year 1995.

FUNDS AVAILABLE

The NIMH expects to support six cooperative agreements funded during fiscal year 1995. The total cost available is \$1.5 million.

RESEARCH OBJECTIVES

Background

The NIMH initiated its "Diagnostic Centers for Psychiatric Linkage Studies" in fiscal year 1989. After rigorous peer review, three centers were selected to plan and coordinate the assessment and collection of data from affected sibling pairs and family members with schizophrenia, three centers for bipolar disorder, and a fourth center for bipolar disorder at the NIMH Intramural Research Program.

Concomitantly, NIMH established a National Cell Repository (Coriell Institute for Medical Research) to store DNA and cell lines immortalized from subjects' blood in addition to a repository of clinical information, the Data Management Center (SRA, Inc). In accord with the assistance aspects of a cooperative agreement, the Principal Investigators retain primary custody of all collected data that include subject identifiers, while anonymous information about family structure, age, sex, and diagnosis is sent to the Data Management Center to form a national resource. Since their primary function is the acquisition and storage of cells and data to be used as a national resource, these repositories were funded through separate contract mechanisms.

Objectives and Scope

This cooperative agreement for genetic analysis of data collected by the Diagnostic Centers for Psychiatric Linkage Studies project is intended to allow participants to: (1) screen DNA from bipolar and schizophrenia families (collected as described above) for potentially relevant mutations; (2) perform the necessary computer simulations using existing family structures and various genetic models to determine optimum analytic strategies as new data become available; (3) search for genes associated with bipolar disorder or schizophrenia, using the best available genetic analytic techniques; and (4) use existing and new highly polymorphic markers to better define the regions where linkages are found. It is anticipated that once genotyping begins these data will be transferred to the data management center on a regular basis.

SPECIAL REQUIREMENTS

Special Requirements, Terms and Conditions of Award, data rights, and arbitration guidelines are explained in the RFA.

Collaborative Responsibilities

The Steering Committee will be the primary decision-making body of this collaborative multi-site study. Membership will be composed of the Principal Investigator from each site including the NIMH Intramural site (one vote per site), and the NIMH Project Coordinator (one vote). The Steering Committee will meet at least three times per year, generally in the Washington, DC Metropolitan Area.

STUDY POPULATION

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

APPLICATION PROCEDURES

Applications are to be prepared on the research grant application form PHS 398 (rev. 9/91). The application form is available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2a of the face page of the application form and the YES box must be marked.

A completed original application and five copies must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

This is a one-time only application with a receipt date of October 19, 1994. Applications received after that date will be returned to the applicant's institutional organization without review. Scientific/technical merit review will take place in November 1994; National Advisory Mental Health Council review will be in early 1995, with a possible start date in March 1995.

REVIEW CONSIDERATIONS

Applications submitted in response to this RFA will be reviewed in accordance with the usual NIH peer review procedures for research grant applications. They will be reviewed for scientific and technical merit by an initial review group (IRG) convened by NIMH and composed primarily of non-Federal scientific experts. A second level of review will be conducted by the National Advisory Mental Health Council.

Review Criteria

Review criteria and award criteria are explained in the RFA.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

David Shore, M.D.
Division of Clinical and Treatment Research
National Institute of Mental Health
5600 Fishers Lane, Room 18C-26
Rockville, MD 20857
Telephone: (301) 443-3683

Direct inquiries regarding grants management to:

Bruce L. Ringler
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-08
Rockville, MD 20857
Telephone: (301) 443-3065

AUTHORITY AND REGULATION

This program is described in the Catalog of Federal Domestic Assistance 93.242, Mental Health Research Grants. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 as implemented through DHHS Regulations at 45 CFR Part 100.

MINORITY INTERNATIONAL RESEARCH TRAINING GRANTS

NIH GUIDE, Volume 23, Number 28, July 29, 1994

RFA AVAILABLE: TW-95-001

P.T. 22, FF; K.W. 0720005

Fogarty International Center
Office of Research on Minority Health

Application Receipt Date: March 15, 1995

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Fogarty International Center (FIC) and the Office of Research on Minority Health (ORMH) support a program to provide international research training opportunities for minority undergraduate students, minority graduate students, and minority faculty members in biomedical and behavioral research.

Training grant awards will be made for three years to U.S. colleges and universities to:

- o encourage minority students to pursue degrees and careers in the biological sciences, especially biomedical and behavioral research, by broadening their undergraduate and graduate education through international experiences;
- o promote qualities of leadership by expanding cultural perspectives in minority students and faculty;
- o help prepare the next generation of scientific leaders to work effectively in a global environment;
- o establish linkages between U.S. scientists and institutions and established centers of biomedical and behavioral research abroad.

ELIGIBILITY REQUIREMENTS

U.S. Participants and Program Requirements:

These institutional training grants will be awarded to U.S. institutions for the purpose of collaborating with one or more foreign research centers that can provide a substantial research training experience for the U.S. minority participants. The applicant institution and any associated institution in a consortium must be a two- or four-year domestic school, college or university.

Minority participants must be from underrepresented minority groups including African Americans, Hispanic Americans, American Indians, and Pacific Islanders. The program director at the applicant institution will be responsible for the selection and appointment of participants, selection of the foreign training site(s) and the overall direction of the training program. Participating students and faculty members must be members of the minority groups listed above and be U.S. citizens or permanent residents who are pursuing degrees, studying and/or conducting research in the biomedical or behavioral sciences at the time of appointment and during the program.

Undergraduate student trainees must be pre-baccalaureate, pursuing a relevant biomedical or behavioral science curriculum, and must show evidence of a commitment to obtaining a postgraduate research related degree in a biomedical or behavioral field of science. The foreign training for undergraduate students will be for approximately 10 to 12 weeks.

Predoctoral students must be enrolled in a U.S. graduate research training program in the biomedical or behavioral sciences. The predoctoral training period at the foreign site may be from approximately 3 to 12 months for the purpose of learning a technique or carrying out a special project or portion of a project related to their doctoral studies.

The minority faculty development portion of the training grant will provide support for research and studies for approximately 3 to 12 months at a foreign training site. Participants must have regular, full-time faculty appointments at the grantee institution or an institution in the consortium. The research plan must indicate the expected benefits of the proposed work.

The foreign research centers should be universities, colleges or other research institutions that have strong, well-established biomedical or behavioral research and research training programs.

MECHANISMS OF SUPPORT

The mechanism of support is the institutional training grant award (T37). Domestic institutions may request up to three years of support. The stipend level during the period of foreign stay is up to \$1,000 per month for undergraduate and graduate students and up to \$3,000 per month for the faculty member. Stipends may be supplemented from non-Federal sources only. The stipend plus the home institution support cannot exceed the appointee's annual salary. Requests may be made for undergraduate and graduate students and faculty of up to \$500 per month each at the foreign training site. Training-related expenses for use at the foreign training site of up to \$500 per month may be requested for each undergraduate student, graduate student, or faculty member. Foreign living expenses will be up to \$1,000 per month for undergraduate and graduate students and up to \$2,000 per month for faculty members.

Stipends, training and travel expenses are offered only for the time period participants are en route to or working in the foreign country. No expenses are provided for domestic research or training. If especially justified, the domestic applicant institution may request up to five percent of the requested total direct costs for the support of the principal investigator and/or other grant-related personnel for domestic administrative efforts. These costs must be specifically related to this grant. Indirect costs will be awarded to the grantee institution at a rate of eight percent of the allowable direct costs. Each of the training grant awards will not exceed a total of \$400,000 per year, including direct and indirect costs.

FUNDS AVAILABLE

It is expected that 6 to 10 new, competitive awards will be made in FY 95.

RESEARCH OBJECTIVES

The Minority International Research Training grants are designed to offer research training grant awards to enable qualified minority undergraduate students, graduate students, and faculty members to participate in international biomedical and behavioral research programs.

This training grant program is expected to attract students and scientists in the developmental stages of their educations and careers to increase their awareness of international research opportunities and to acquaint them with the full range of career opportunities in biomedical and behavioral research.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies. All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (59 FR 14508-14513) and printed in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) using the special instructions related to Institutional National Research Service Awards (Section VII). Note the requirement to use NRSA substitute pages MM, NN, OO to be acceptable for initial review. Application kits are available at most institutional offices of sponsored research and may also be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

The completed application and three legible copies must be sent or delivered to the following address and received by March 15, 1995:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

In addition, two copies of the completed application must be sent to Dr. Wolff at the address listed under INQUIRIES.

REVIEW CONSIDERATIONS

All applications responding to this RFA will be reviewed for scientific and technical merit by an NIH initial review group, followed by a second level review by the Fogarty International Center Advisory Board. To be eligible for review, applications must be complete and submitted in accordance with the application procedures stated above. Letters from the foreign collaborators and their institutional officials indicating their willingness to participate in this training program must accompany the application. The review criteria are listed in the RFA.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct inquiries regarding programmatic issues and two copies of the application to:

Dr. David Wolff
International Research and Awards Branch
Fogarty International Center
Building 31, Room B2C39
Bethesda, MD 20892
Telephone: (301) 496-1653
FAX: (301) 402-0779

Direct inquiries regarding fiscal matters to:

Ms. Silvia Mandes
International Research and Awards Branch
Fogarty International Center
Building 31, Room B2C39
Bethesda, MD 20892**
Telephone: (301) 496-1653
FAX: (301) 402-0779

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.106. Awards are made under the authority of the Public Health Service Act, Title III, Part A, Section 307b (42 USC 2421) and administered under PHS grants policies and Federal regulations, most specifically 42 CFR part 61. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or to Health Systems Agency review.

INVESTIGATOR-INITIATED INTERACTIVE RESEARCH PROJECT GRANTS

NIH GUIDE, Volume 23, Number 28, July 29, 1994

PA NUMBER: PA-94-086

P.T. 34; K.W. 0710030, 1014006

National Institute on Alcohol Abuse and Alcoholism
 National Institute on Aging
 National Institute of Allergy and Infectious Diseases
 National Institute of Arthritis and Musculoskeletal and Skin Diseases
 National Cancer Institute
 National Institute of Child Health and Human Development
 National Institute of Dental Research
 National Institute of Diabetes and Digestive and Kidney Diseases
 National Institute on Drug Abuse
 National Institute of Environmental Health Sciences
 National Library of Medicine
 National Institute of Mental Health
 National Institute of Nursing Research
 National Center for Research Resources

Application Receipt Dates: February 15, June 15, October 15

Introduction: This is to rescind NIH PA-93-078, on Investigator-Initiated Interactive Research Project Grants (Volume 22, Number 16, April 23, 1993), and replace it with the following Program Announcement.

The purpose of this revised Program Announcement is to clarify several important aspects of the Interactive Research Project Grant (IRPG) program, as originally announced in the NIH Guide for Grants and Contracts, Vol. 22, No. 16, April 23, 1993. The full text of the revised Program Announcement, which replaces and supersedes the original text, is available electronically, as well as from the Institute or Center contacts listed under INQUIRIES. In addition, a new brochure, "Special Instructions for Preparing Applications for Investigator-Initiated Interactive Research Project Grants," is available from the Office of Grants Information, Division of Research Grants, NIH, 301/594-7248, and from the Institute or Center contacts.

The key clarifications in this revised Program Announcement are as follows:

1. The important characteristics of IRPG applications and their differences from Program Projects are explained more clearly.
2. The section on STUDY POPULATIONS has been updated to reflect the latest NIH policy required under the NIH Revitalization Act of 1993 and announced in the Federal Register of March 28, 1994 (FR 59 14508-14513), and printed in the NIH Guide for Grants and Contracts, Vol. 23, No. 23, March 18, 1994. All applications received on or after June 1, 1994 must conform to this new policy.
3. The requirements for format and layout of each application in the IRPG group have been stated more clearly.
4. The procedures for submission of applications and the receipt dates for applications, including AIDS and AIDS-related applications, have been clarified.
5. The guidelines for requesting limited shared resources for projects in the IRPG group have been clarified.
6. The special instructions for preparation of Section 7, Consultants/Collaborators, of the Research Plan have been clarified.
7. Table II, Distribution of Effort of All Personnel in the IRPG, is no longer required.
8. The process for referral of the applications and the review criteria for the collaborative arrangements have been clarified.

PURPOSE

Certain questions in biomedical and behavioral research require research efforts that extend beyond the level practicable in a single project or require a variety of technical approaches beyond the means of a single investigator. There may be areas of investigation that are under-represented in individual research project grant (R01) and First Independent Research Support and Transition (FIRST) (R29) award applications because of the lack of available collaborative effort on a local level. Further, the perceived merit of individual projects may be diminished by the lack of a comprehensive, interdisciplinary approach or by limitations in resident technical expertise.

The National Institutes of Health (NIH) has used many ways to encourage strong collaboration among research scientists. These have ranged from specific interaction of the Federal government with academia/industry through contract or cooperative agreement solicitations to Requests for Applications (RFAs) that solicit research applications involving various forms of cooperation among applicants. This Program Announcement provides for a new kind of formal interaction, based on the initiative of applicants, to enhance existing interactions with colleagues or to develop new collaborative relationships.

The Interactive Research Project Grant (IRPG) program encourages the coordinated submission of related research project grant (R01) and, to a limited extent, FIRST award (R29) applications from investigators who wish to collaborate on

research, but do not require extensive shared physical resources. These applications must be scientifically interrelated in some manner and must describe the objectives and scientific importance of the interchange of, e.g., ideas, data, and materials, among the collaborating investigators. A minimum of two independent investigators with related research objectives are encouraged to submit concurrent, collaborative, cross-referenced individual R01 and/or R29 applications. The proposed projects must not be dependent upon each other to the extent that one could not be accomplished in the absence of the other. Applicants may be from one or several institutions. Applications will be reviewed independently for scientific merit. Applications judged to have significant and substantial merit will be considered for funding both as independent awards and in the context of the proposed IRPG collaboration.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions, however, are not eligible for the R29 award. Applications may be submitted from one or more institutions. Applications from or involving minority institutions, minority individuals, and women are encouraged.

Applicants for IRPG awards may not concurrently submit additional R01 or R29 applications (either investigator-initiated or in response to an RFA) that represent significant duplication of the efforts described in the IRPG. Concurrent submission of program project (P01) or cooperative agreement (U01, U10, U19, etc.) applications requesting support for essentially similar work also is prohibited.

MECHANISM OF SUPPORT

Support of this program will be by the traditional research project (R01) grant and the FIRST (R29) award. The IRPG group must consist of a minimum of two independent applications. An IRPG package may consist of a combination of R01 and R29 applications, or R01 applications only, but may not consist solely of R29 applications. Applications for both new (Type 1) and competing renewal (Type 2) awards may be submitted as IRPGs.

Occasionally, Institutes and Centers of the NIH may issue additional Program Announcements that include IRPGs. The RFA also may be used, in limited circumstances, to solicit applications for IRPG awards in a discrete scientific area. Although the level of interaction for IRPGs between or among applicants in these solicitations will conform to those outlined here for the investigator-initiated IRPG, there may be minor differences outlined in the RFA. For example, all RFA solicitations will specify a single receipt date that will be different from those listed in this program announcement.

All Public Health Service (PHS) and NIH grants policies will apply to applications received in response to this program announcement.

This revised program announcement supersedes any previous program announcements regarding IRPG awards. Future IRPG applications must follow the instructions presented in this program announcement.

RESEARCH OBJECTIVES

The NIH encourages qualified independent investigators to develop and submit coordinated R01 and R29 applications that address any research area supported by the Institutes or Centers listed above. The IRPG program could be used constructively to support collaborative efforts designed to accelerate the development of fundamental knowledge and/or enhance the clinical application of that knowledge. The IRPG award may fit well with clinical applications that propose limited, testable research questions or focused therapeutic and related correlative laboratory studies. However, the IRPG program is not appropriate for large epidemiologic studies or multi-institutional clinical trials using common protocols.

If there is a question about the appropriateness of a set of applications for the IRPG program, applicants are encouraged to discuss the issues with NIH staff contacts listed under INQUIRIES.

IRPG Characteristics

The IRPG application consists of a number of investigator-initiated projects that share an aspect of relationship of objectives. The projects may involve several institutions and may be interdisciplinary. The IRPG program is intended to promote collaborative efforts between or among projects, while providing a record of independently acquired awards credited to each individually funded investigator and allowing retention of research autonomy by the named Principal Investigator (PI) of each project. Each grantee will have the ability to submit on his/her behalf competing supplements as appropriate to incorporate promising new directions of research as they evolve. The freedom to establish collaborations on an equal footing at separate sites (including foreign locations, with the exception that only domestic organizations and institutions are eligible to receive FIRST (R29) awards), and the transferability of awards made to individual investigators, are other benefits. Nevertheless, each investigator may benefit, because the IRPG award establishes a larger framework of reference for the proposed work and facilitates formal collaborations tailored to achieving investigator-initiated research objectives.

Thus, the IRPG application must demonstrate a sense of collaboration toward related goals. It must describe how the participants intend to take the opportunity to participate in mutually-beneficial interactions, while maintaining the independence of their projects. The IRPG application may involve utilization of shared resources in advancing effective collaborations. It is important for each individual application comprising a portion of the overall IRPG to describe the proportion of the shared resources needed for that individual project.

Since each component R01 and R29 is an independent application, it should be prepared in the same level of detail and with the same care as a traditional R01 or R29 application. Each project also should be able to stand on its own scientifically; the projects proposed must not be dependent on each other, but should be designed so that they could be accomplished independently. For example, one project should not be completely dependent on another project for provision of a critical chemical or reagent, testing or processing of key samples, or interpretation of data.

Comparison with Program Projects

Historically, the NIH has relied on multi-component awards, such as program projects (P01), center grants (P30, P50), and cooperative agreements (U01) to encourage multi-disciplinary collaboration in areas requiring integration and coordinated direction of basic and clinical research components. In general, such awards include the provision of extensive core facilities/resources and appointment of a program director to manage the overall effort.

However, for many research areas it may be appropriate to consider an intermediate level of collaboration that is beyond that practicable for single projects. For such scientifically originated collaborative efforts, the exchanges of data, materials, and ideas, rather than shared extensive physical resources or central oversight, are the primary requirement. The concept of the IRPG put forth in this program announcement is meant to address and facilitate this class of research activity.

The IRPG allows interaction to be initiated among applicants, as is the case with a program project grant (P01) application, but the IRPG differs from the P01 in important ways. The IRPG group consists of investigator-initiated applications on related but independent topics, with a formalized agreement to collaborate in specific ways. The collaboration may include limited shared scientific resources. The IRPG program can be useful where interdependency among efforts is not a requirement, but where the intended collaboration would enhance goal achievement. The IRPG application must provide for interaction between or among the investigators arising from their desire to collaborate as independent investigators. The scope of research in each component of a successful IRPG group should be greater than could be achieved without the collaboration. The proposed collaborations should have a demonstrable impact on ability of the investigators to achieve the projects' goals.

In contrast, the P01 has a well-defined major objective or central theme, most commonly incorporates collaborative efforts among investigators from the same institution, may involve significant core resources, and is under the direct control of a central principal individual with authority over research direction and budget. If significant core resources beyond a limited amount are needed, applicants should consider applying for a P01.

STUDY POPULATIONS

If human subjects are involved, each component application must address these issues.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minority in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and reprinted in the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994. Investigators may obtain copies from these sources or from the contact person listed below. The contact person may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). These forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

Before preparing an IRPG application, applicants should obtain the brochure "Special Instructions for Preparing Applications for Investigator-Initiated Interactive Research Project Grants," available from the Office of Grants Information, Division of Research Grants, NIH, 301-594-7248, and from the Institute or Center contacts.

Each application must be identified by checking "YES" on line 2a of the PHS 398 face page, citing this IRPG program announcement number, and including the title: "Investigator-initiated IRPG."

All requirements with regard to type size, page limitations, appendix material, etc., must be followed or applications will be returned without review. FIRST applications (new and revised) must be accompanied by three letters of reference. FIRST applications without these letters will be considered incomplete and will be returned without review.

IRPG applications, whether new (Type 1), competing renewal (Type 2), or revised applications, will have common receipt dates as shown in the table below. Receipt dates for AIDS and AIDS-related applications also are given. For each component IRPG application, a signed, printed original, five exact single-sided copies, and five sets of appendix material must be submitted.

Each application must be complete in itself, with all necessary approvals, budgets, and signatures from the appropriate officials of the applicant institution. Each application must have its own descriptive title and a separate Principal Investigator. Since each component project of an IRPG application is an independent R01 or R29 application, the component projects should NOT be presented as subcontracts to one parent project. Each requested shared resource must be included in one of the component applications; no shared resource may be submitted separately. If the shared resource is in other than an applicant institution, the shared resource may be supported as a subcontract to one of the component institutions.

All information about the interactive nature of the projects should be included in a subsection of Section 7 of the Research Plan of each component IRPG application. Specific detailed instructions for completing all parts of Section

7 of the Research Plan, are provided in the brochure, "Special Instructions for Preparing Applications for Investigator-Initiated Interactive Research Project Grants." In addition to a description of project-specific collaborations, each component application of the IRPG Group must contain an identical subsection (entitled "IRPG INTERACTIONS") and identical information showing utilization of any requested shared resources. The IRPG INTERACTIONS subsection of Section 7 should address the intended interactions among the component projects of the IRPG group and the perceived benefits of supporting all of the components of the IRPG group as a combined effort.

Description of the shared resources that will be supported through one of the IRPG component applications, if any, should be inserted as a separate section of the application after Section 8 (Consortium/Contractual Arrangements) of the Research Plan and before Section 9 (Literature Cited). As described in detail in the instructions brochure, this should include an explicit description of the methods and procedures to be used, the services, tests, animals, facilities, etc. to be provided, and a description of the involvement and protection of human subjects or vertebrate animals, if appropriate. Extensive shared resources, or those with large budgets, may be more appropriate for full-fledged Cores in program projects. Applicants are urged to contact the NIH staff listed under INQUIRIES to discuss the nature and extent of proposed shared resources in an IRPG group. In no case should a resource be submitted as a separate application.

All R01 or R29 applications constituting the proposed IRPG cohort must be submitted in a single package, whether or not the applications arise from the same institution. Each application within the package must be clearly identified and a cover letter must list the total number of applications submitted for the IRPG cohort, indicating the Principal Investigator of each. The various projects comprising the IRPG application should not be collated together, as is done for a program project. For each application of the IRPG group, the original, five copies, and the appendix material must be bundled together and clearly identified.

If two or more, but not all, applications within an IRPG Group receive initial funding as an IRPG, and unfunded applications within that group are subsequently amended and submitted on later receipt dates, the awarded IRPG component(s) should be identified and may be cited in the amended applications. In such cases, those amended R01/R29 applications must make reference to being part of a partially funded IRPG. They may, however, request support to extend beyond the end date of the already awarded component R01(s), consistent with the scientific goals of the application.

Revised applications should highlight the changes made in the Research Plan in response to the previous critique, and also should indicate in Section 7 how the delay in initiating the collaboration will be addressed. This is particularly important if some projects in the IRPG group were awarded and research on those projects already has begun.

If the IRPG group is not fundable as such, any individual application within the IRPG group may be considered as a possible candidate for funding as an individual R01.

IRPG Receipt and Review Schedule

Application Receipt Date:	Feb 15	Jun 15	Oct 15
Initial Review:	Jun	Oct	Feb
Council Review:	Sep/Oct	Jan/Feb	May/Jun
Anticipated Date of Award:	Dec 1	Apr 1	Jul 1

Instructions for AIDS and AIDS-related applications

IRPG applications for AIDS-related research must be identified as such, and should be submitted in accordance with the AIDS expedited review process. The receipt and review schedule for AIDS-related IRPG applications is given below.

Application Receipt Date:	Jan 2	May 1	Sep 1
Initial Review:	Mar/Apr	Jul	Nov
Council Review:	May/Jun	Sep/Oct	Jan/Feb
Anticipated Date of Award:	Jul 1	Dec 1	Apr 1

Failure to follow the instructions regarding submission date and packaging may lead to a delay in review.

The IRPG application package must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Any questions regarding the format for submission of an IRPG package may be directed to the Referral Office, Division of Research Grants, Westwood Building, Room 248, telephone (301) 594-7250.

REVIEW CONSIDERATIONS

Upon receipt, applications and supporting material will be examined by the Division of Research Grants for completeness. Incomplete applications will be returned without further consideration.

Each application in an IRPG Group will be referred to the most appropriate Initial Review Group (IRG), according to standard NIH referral and review procedures, for scientific and technical merit review. The IRG could be either a DRG Study Section or an Institute or Center-managed review committee, depending on the referral guidelines for the particular research proposed. Since applications in the IRPG might be referred to different IRGs, the IRPG INTERACTIONS part of Section 7 must be complete so that reviewers can understand the collaborations and interactions without necessarily seeing any of the other applications in the Group. Following scientific and technical merit review, applications that may be considered for award will receive a second level review by the appropriate national advisory council(s).

Institute or Center assignment of each component application in the IRPG also will be governed by established PHS referral guidelines. Therefore, depending on the subject matter of each IRPG, it is possible that the component

applications will be assigned to different NIH Institutes or Centers for funding consideration. This underscores the need for each application to be complete within itself and for all component applications to have identical subsections on IRPG INTERACTIONS in Section 7 of the Research Plan. As with any R01 or R29 application, each component of the IRPG Group must be able to stand on its own merit. Consequently, the application must be prepared with the same detail as a traditional R01 or R29 application.

The initial review for scientific and technical merit will focus on each application independently, using standard review criteria for R01 and R29 applications generally, and each application will be assigned its own priority score. In addition, the reviewers will read Section 7 and will assess the intended IRPG interactions. In an Administrative Note, the reviewers will indicate the effectiveness and feasibility of the proposed IRPG interactions and whether they enhance the prospects for reaching the stated objectives of the Group, and the extent of synergy between the various projects derived from the interactions. The appropriate national advisory council or board and the program staff in the Institute or Center to which the applications are assigned will consider these comments on the proposed collaborations in making award decisions.

The IRG will evaluate the requested Shared Resource component(s) in the application (qualifications of key personnel; adequacy of approaches, methods, and facilities; appropriateness for the IRPG Group; and utilization by component IRPGs) independently from the research project. The IRG may also make recommendations about the Shared Resource(s) or the reasonableness of the budget. These recommendations will be taken into account when funding decisions are made by the awarding Institute or Center. The actual amount of Shared Resource(s) awarded may depend on the number of component projects actually awarded.

AWARD CRITERIA

Applications will compete for available funds with all other applications found to have significant and substantial merit. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o The interactive nature of the program and of the component IRPGs
- o Availability of funds
- o Program balance among research areas

Each Institute or Center will have the opportunity to fund some or all of the component IRPG applications assigned to it. If the components are assigned to more than one Institute or Center, co-funding may be considered. If some component IRPG applications are considered not supportable, the collaborative plans may need to be changed. If an Institute or Center chooses to fund an entire IRPG package, a review of the collaborative plans in toto will be conducted by an appropriate advisory council. As stated above, if the IRPG group is not fundable as such, any individual application within the IRPG group may be considered as a possible candidate for funding as an individual R01 or R29.

INQUIRIES

Additional written instructions for the preparation of applications are available upon request. This document, "Special Instructions for Preparing Applications for Investigator-Initiated Interactive Research Project Grants," is available from the Office of Grants Information, Division of Research Grants, NIH, 301-594-7248. Applicants should be aware that not all Institutes or Centers are participating in this program. Contact any of the following individuals for further information:

Dr. Kenneth Warren
Director, Office of Scientific Affairs
National Institute on Alcohol Abuse and Alcoholism
Telephone: (301) 443-4375

Dr. Miriam Keltz
Associate Director, Extramural Affairs
National Institute on Aging
Telephone: (301) 496-9322

Mr. Allan Czarra
Director, Office of Program Coordination and Operations
National Institute of Allergy and Infectious Diseases
Telephone: (301) 402-0160

Dr. Michael Lockshin
Director, Extramural Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases Telephone: (301) 496-0802

Dr. Marvin Kalt
Deputy Director, Division of Extramural Activities
National Cancer Institute
Telephone: (301) 496-4218

Ms. Hildegard Topper
Special Assistant to the Deputy Director
National Institute of Child Health and Human Development
Telephone: (301) 496-0104

Dr. Norman Braveman
Assistant Director for Program Development
National Institute of Dental Research
Telephone: (301) 594-7648

Dr. Walter Stolz
Director, Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Telephone: (301) 594-7277

Ms. Eleanor Friedenberg
Director, Office of Extramural Program Review
National Institute on Drug Abuse
Telephone: (301) 443-2755

Dr. Thor Fjellstedt
Deputy Director, Division of Extramural Research and Training
National Institute of Environmental Health Sciences
Telephone: (919) 541-0131

Dr. Milton Corn
Acting Associate Director, Division of Extramural Programs
National Library of Medicine
Telephone: (301) 496-4621

Dr. Hugh Stamper
Director, Division of Extramural Activities
National Institute of Mental Health
Telephone: (301) 443-3367

Dr. Theresa S. Radebaugh
Director, Division of Extramural Programs
National Institute of Nursing Research
Telephone: (301) 594-7590

Dr. Louise Ramm
Deputy Director
National Center for Research Resources
Telephone: (301) 496-6023

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.113, 93.114, 93.115, 93.121, 93.198, 93.306, 93.333, 93.371, 93.393, 93.394, 93.395, 93.396, 93.397, 93.847, 93.848, 93.849, 93.855, 93.856, 93.864, 93.865, 93.929, 93.866, 93.879, 93.361, 93.846, 93.242, 93.273, and 93.279. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NEUROENDOCRINOLOGY OF AGING

NIH GUIDE, Volume 23, Number 28, July 29, 1994

PA NUMBER: PA-94-087

P.T. 34; K.W. 0710010, 0785105

National Institute on Aging
National Institute of Diabetes and Digestive and Kidney Diseases

PURPOSE

The National Institute on Aging (NIA) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) announce an ongoing interest in supporting basic and clinical research addressing aging of neuroendocrine systems and their sequelae. Mechanistic approaches at either the organismic, cellular, or molecular levels are encouraged.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Neuroendocrinology of Aging, is related to the priority area of aging and the increasing years of healthy productive life. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Awards will be administered under PHS grants policy as stated in the PHS Grants Policy Statement, DHHS Publication No.

NIH Guide for Grants and Contracts - Vol. 23, No. 28 - July 29, 1994

RESEARCH OBJECTIVES

Background

Research accumulated over the past decade has solidified the view that changes in neuroendocrine control systems underlie the wide range of impaired body functions normally associated with advanced chronological age. The major challenge that now faces investigators in the field is to understand more clearly how deficits in brain-pituitary function arise with age, and the relationship of these deficits to imbalances in peripheral organ system homeostatic control.

The maintenance of homeostasis in the face of environmental stress is largely under the control of the neuroendocrine system. With age, there appears to be a decreased capacity to adapt to changes in the environment. Frequently, the response is delayed and of lower magnitude in the older individual. These responses are mediated primarily through the neuroendocrine system. Thus, it is important to identify and elucidate the mechanisms underlying age-related changes in the neuroendocrine system, and conversely, to understand and to characterize how the endocrine system impinges upon and controls the nervous system.

For example, circadian and other biological rhythms are central to these homeostatic processes. At least some of these rhythms are coupled to circadian fluctuations in the secretion of aminergic and peptidergic neurotransmitters as well as pituitary hormones. Blended on top of these daily rhythms in hormone release are more frequent ultradian fluctuations. To date, few data exist that examine the relationship between circadian rhythms and the shorter ultradian rhythms. Such information is critical since disruption of the central timing mechanism governing circadian rhythms such as sleeping and eating as seen in older individuals could underlie a cascade of age-associated changes in neuroendocrine function, and in particular, pulsatile hormone release, which could compromise processes involved in growth, metabolism, and reproduction.

The NIA also continues to encourage research leading to a better understanding of the menopause and its sequelae. It has long been thought that menopause, or the cessation of regular reproductive cycles, is due to the exhaustion of ovarian follicles with aging. More recently, it has become clear that the decline in reproductive function that occurs in aging may also be due to age-related disruption of the biological clock, which results in altered secretion and secretory patterns of neurotransmitters and hormones and altered gene expression in cells producing these substances. Thus, research focusing on the identification and elucidation of the mechanisms underlying the neuroendocrine etiologies of menopause are encouraged.

It has been proposed that age-related degeneration in certain central nervous system (CNS) tissues can be related, in part, to the neurotoxic effect caused by their repeated exposure to circulating steroids. This has been most evident in the relationships between corticosteroids and estrogens to hippocampal and hypothalamic degeneration, respectively. Additional research is needed to further explore and delineate the processes potentially responsible for these neurodegenerative disorders associated with aging.

Estrogen receptor mRNA has been demonstrated to be distributed in the adult rat brain not only in regions that are known targets of estrogen, such as the hippocampus and the hypothalamic preoptic nuclei, but also in regions not typically considered as targets for estrogen action such as the basal forebrain. Recent findings indicate that estrogen receptors colocalize with neurotrophin receptors in cholinergic neurons within the basal nucleus of Meynert, suggesting that estrogen may modulate the functioning of these cells that form part of the neural substrate of cognition. Colocalization of estrogen and nerve growth factor receptors also have been found in the dorsal root ganglia of adult female rats; the expression of both classes of receptors were regulated by estrogen, supporting the hypothesis that estrogen may play a functional role in the regulation of neuronal responsiveness to neurotrophins. Further research is required to elucidate these estrogen-neurotrophin interactions.

Furthermore, it is becoming more evident that cytokines produced by various immune tissues may affect the neuroendocrine axis. These cytokines can be released either into the bloodstream or in the local vicinity of nervous tissue to exert their actions. This bidirectional communication between the immune and endocrine systems is paramount to homeostatic control. Noting the well-documented decline in the function of both these systems with age, it would seem that senescence could alter the precise balance in immune-endocrine communication. Consequently, research is encouraged to examine potential consequences of the aging immune and endocrine systems and their interactions on neuroendocrine function.

The NIDDK has long been interested in understanding the interrelationships between the hypothalamic-pituitary-adrenal/gonadal axes and the immune system in response to stress and disease. The NIDDK is acutely aware of the role(s) played by external sensory inputs, related through these axes, on circadian and ultradian cycles of hormonal and behavioral regulation. The NIDDK also continues to foster research on the roles of both members of the steroid/thyroid/retinoid supergene family and growth factors on brain function.

To help identify opportunities for further research in this area, the NIA convened a workshop on the Neuroendocrinology of Aging: Perspectives and Prospectives. The proceedings of this meeting have been published in *Neurobiology of Aging*, 15(4), 1994

Specific Goals and Scope

To address the general objectives discussed above, NIA and NIDDK encourage submission of applications for research relating to the neuroendocrinology of aging that address one or more of the following areas, which are illustrative and are not intended to be restrictive.

- o Investigations of the molecular and cellular processes modulating the aging hypothalamic neuroendocrine system, as well as the mechanisms causing neuroendocrine decline with age.
- o Elucidation of the mechanisms underlying the loss of, or alterations in, neuroendocrine rhythms with age.
- o Studies of how the aging circadian system acts upon ultradian hormone rhythms (e.g., pulsatile hormone release).

- o Identification of the effects of systemic steroids (e.g., glucocorticoids, estrogens) on cytoarchitecture and synaptic organization and remodeling, and the elucidation of the mechanisms of action of hormones on neural cells.
- o Evaluation of steroid antagonists or agonists as a means to mitigate or delay potential neurotoxic consequences of steroid exposure.
- o Investigation of CNS mechanisms that may alter the rate of reproductive senescence.
- o Studies of how networks of organ systems that share signal molecules, such as the endocrine, immune, and nervous systems, mutually regulate their complex interactions, and whether alterations in these interactions result in impaired neural homeostatic controls leading to increased likelihood of pathologies and disease.
- o Determination of the mechanisms controlling the effects of dietary restriction on the neuroendocrine system.
- o Identification of the roles and underlying mechanisms played by the hypothalamic neuroendocrine system in the aging process, and establishment of whether neuroendocrine interventions can inhibit or reverse the aging process.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the National Institutes of Health (NIH) that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 9, 1994 (FR 59 11146-11151) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit. The receipt dates for applications for AIDS-related research are found in the PHS 398 instructions. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The title and number of this program announcement must be typed in Section 2a on the face page of the application.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director or principal investigator could be included with the application.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be reviewed for scientific and technical merit in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by an appropriate National Advisory Council.

The following criteria will be used in evaluating applications submitted in response to this program announcement:

- o Scientific and technical merit, significance, and originality of the proposed research;
- o Appropriateness and adequacy of the experimental approach and methodology to be used;
- o Qualifications of the principal investigator and staff in the area of research, and the principal investigator's prior research experience and record;
- o Adequacy of the available facilities.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that Institute, Center, or Division. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Andrew A. Monjan, Ph.D., M.P.H.
Neuroscience and Neuropsychology of Aging Program
National Institute on Aging
Gateway Building, Suite 3C307
Bethesda, MD 20892
Telephone: (301) 496-9350
FAX: (301) 496-1494

Phillip Smith, Ph.D.
Endocrine and Metabolic Diseases Program Branch
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 621
Bethesda, MD 20892
Telephone: (301) 594-7531
FAX: (301) 594-9011

Direct inquiries regarding fiscal matters to:

Vicki Maurer
Grants and Contracts Management Office
National Institute on Aging
Gateway Building, Suite 2N212
Bethesda, MD 20892
Telephone: (301) 496 1472

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.866, Aging Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MALNUTRITION IN OLDER PERSONS

NIH GUIDE, Volume 23, Number 28, July 29, 1994

PA NUMBER: PA-94-088

P.T. 34; K.W. 0710010, 0710095

National Institute on Aging

PURPOSE

Recently, attention has focused on the nutritional status and nutrition-related needs of older individuals in this country. Nutritionists have indicated that a substantial proportion of Americans over the age of 50 have dietary intakes or diseases that place them at a high risk of malnutrition. The limited available information estimates levels of malnutrition ranging from 10 to 60 percent. The purpose of this Program Announcement is to encourage research into the extent, causes and potential interventions in malnutrition in the elderly.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Malnutrition in Older Persons, is related to the priority area of nutrition. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-00473-1) through the superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, unit of State and local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged. Only R01 application will be

MECHANISM OF SUPPORT

Support of this program will be through the research project grant (R01), FIRST (R29) award, and Research Scientist Development (K01) award. Awards will be administered under PHS grants policy as stated in the Public Health Service Grants policy statement, DHHS Publication No. (OASH) 94-50,000 (rev. 4/1/94). The NIA has a Special Emphasis Research Career Award (K01): "Nutritional and Metabolic Factors in Aging"

RESEARCH OBJECTIVES

Background and Significance

Considerable epidemiologic data indicate that malnutrition may be common among older persons, and may have important morbid consequences. Malnutrition may be due either to under- or over-consumption of macro- or micro-nutrients or calories. Both of these may be important among older persons. In addition, changes in nutrient absorption or metabolism, which may be introduced at different levels within the organism (i.e., gut, muscle, brain), and may be either idiopathic or due to age-related diseases, may contribute to malnutrition among older persons even when intake of nutrients is within recommended limits for the general public. Such age-related changes may occur chronically, or may be manifested in response to acute conditions such as infection, surgery, or trauma.

National survey data show that large percentages of community-dwelling older persons consume less than the recommended amounts of several micronutrients. Data on residents of nursing homes, hospitalized older patients, as well as community elderly populations, show a high prevalence of persons with low body mass index and other findings consistent with the possibility of protein energy malnutrition. (To date there is limited information on the clinical consequences of many of these nutritional findings per se.) Conversely, many older persons may consume some nutrients, e.g., fat, well in excess of current recommendations. The health effects of such consumption are also incompletely understood. Recommendations for increased physical activity by older persons may alter nutrient requirements, incurring the risk of malnutrition if diet is not modified accordingly.

There have been few controlled randomized studies on the efficacy of nutritional supplementation or other dietary modification on clinical outcomes in malnourished older patients. In addition, data indicate that a substantial amount of malnutrition in older persons may be due to diminished food intake spanning all nutrient categories. Although some known risk factors (e.g., depression) undoubtedly explain this phenomenon in some older patients, the causes of diminished food intake in older persons are not completely understood. Although some pharmacologic agents (e.g., megestrol) and non-pharmacologic approaches (e.g., exercise) may lead to increased food intake, there are almost no data on the effects of such interventions on food consumption in undernourished older persons.

Objectives

The NIA continues to encourage research on the full spectrum of issues related to the causes, prevention, and treatment as well as the socio-behavioral and economic aspects related to malnutrition in older persons. Specific topics of interest include, but are not limited to, studies on:

- o Evaluation of nutritional assessment criteria and instruments used in elderly people. Currently available methods have not necessarily been validated in aging populations. Screening and intervention measures differ, depending on standards used to judge if an individual is malnourished, and present standards are intended for younger adults.
- o Age-associated alterations in absorption and metabolism of essential nutrients, dietary factors, and metabolic processes that may contribute to malnutrition.
- o The effects of age on neurons of the satiety centers that influence and regulate appetite and thirst, as well as the effect of changes in sensitivity and acuity, or receptor thresholds for sensory stimulation, especially olfaction and taste, associated with hedonic behaviors.
- o Mechanism for predisposition to dehydration in older persons and implication of dehydration in terms of clinical symptoms and medical outcomes.
- o The effects of malnutrition on specific central nervous system cell types, including, in addition to neurons, the neuroglia and cerebrovascular cells.
- o Gender differences in the metabolism of macro- and micro-nutrients during the late stages of development and in aging in both the so-called healthy aging or malnourished individual.
- o Effects of under- or over-consumption (in relation to current recommended levels) of calories or specific nutrients on risk of acute or chronic diseases in older persons (e.g., infections, cardiovascular diseases) and mechanisms responsible for these effects.
- o Influence of medications commonly prescribed for the elderly on aspects of nutrition.
- o Effects of nutritional supplementation or other dietary modification on clinical outcomes in well-characterized specific populations of malnourished older persons. Studies in acute situations (e.g., recovering hospitalized patients) and in chronic conditions (e.g., chronic weight loss) are encouraged.
- o Causes of pathologically low food intake in older persons e.g., identification of forms of malnutrition in the elderly such as "anorexia dementia" or feeding dependency.
- o Efficacy of interventions to increase spontaneous food intake (drugs, exercise) in undernourished patients in negative energy balance, and effects of different levels and types of exercise and physical activity on nutrient needs of older persons.

- o The role of socio-economic, cultural or behavioral factors as predictors of malnutrition, as well as modifiers of any diagnosis/treatment plans.

- o Evaluation of efficacy and cost-effectiveness of screening for malnutrition in the free-living, hospitalized and long-term care elderly populations

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 9, 1994 (FR 59 11146-11151) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91), available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. New applications will be accepted on February 1, June 1, and October 1 receipt dates. Revised applications will be accepted on March 1, July 1, and November 1. The program announcement title and number must be typed on line 2a of the face page.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review. The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be received by the NIH Division of Research Grants. The review criteria are the traditional considerations underlying scientific merit. Applications will be reviewed in accordance with the usual NIH peer review procedures, based on scientific merit. Following study section review, the applications will be evaluated by the appropriate National Advisory Council.

AWARD CRITERIA

Applications will compete for available funds on the basis of scientific merit with all other applications assigned to the institute. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Pamela Starke-Reed, Ph.D.
Biology Of Aging Program
Gateway Building, Suite 2C231
National Institute on Aging
Bethesda, MD 20892
Telephone: (301) 496-6402

Direct inquiries regarding fiscal matters to:

Mr. Robert Pike
Grants Management Office
National Institute in Aging
Gateway Building, Suite 2N212
Bethesda, MD 20892
Telephone: (301) 496-1472

This program is described in the Catalog of Federal Domestic Assistance No. 93.866, Aging Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MECHANISMS OF SENSORIMOTOR ADAPTATION

NIH GUIDE, Volume 23, Number 28, July 29, 1994

PA NUMBER: PA-94-089

P.T. 34; K.W. 0705048, 0775017

National Institute on Aging
National Institute on Deafness and Other Communication Disorders
National Institute of Neurological Disorders and Stroke
National Aeronautical and Space Administration

PURPOSE

The National Institute on Aging (NIA), National Institute on Deafness and Other Communication Disorders (NIDCD), National Institute of Neurological Disorders and Stroke (NINDS), and National Aeronautics and Space Administration (NASA) announce a continuing interest in supporting ground-based studies of sensorimotor adaptation and multisensory integration focusing on such functions as posture, gait, and other limb and body spatially directed movements, in health, in disease, and in special gravito-inertial environments.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement (PA), Mechanisms of Sensorimotor Adaptation, is related to the priority area of aging and balance impairment, a significant cause of morbidity and disability in older individuals. Potential applicants may obtain a copy of "Healthy People-2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are ineligible for First Independent Research Support and Transition (FIRST) (R29) awards. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Awards will be administered under PHS grants policy as stated in the PHS Grants policy statement, DHHS Publication No. (OASH) 94-50,000 (rev. 4/1/94). Research will be supported by the research project grants (R01) and FIRST awards (R29) mechanisms.

RESEARCH OBJECTIVES

Problems associated with impaired balance, such as falls and restricted ambulation, are prominent causes of morbidity and disability among older persons. Correspondingly, problems associated with balance control and spatial orientation are important in connection with space flight. During aging and during exposure to the microgravity environment of space, sensorimotor functions may be similarly challenged. Changes and ambiguities in the processing of sensory inputs lead to potential errors in cognition and perception affecting equilibrium and spatial orientation. Errors in reflexes and perceptions can lead to dysfunctional consequences, such as falls in the elderly and space motion sickness in astronauts. Human spatial orientation and spatially directed motor performance is facilitated by the central nervous system integrating multiple sensory inputs and initiating appropriate motor commands. Under natural terrestrial conditions, the visual, vestibular, tactile, somesthetic, and auditory sensory systems interact in a highly adaptive fashion; the functional importance of individual systems is modulated by intrinsic and extrinsic conditions.

Aging and exposure to microgravity both entail sensory and motor modifications that stimulate neuroplastic mechanisms to restore, or compensate for, compromised function. In the older individual, natural aging involves slow structural deterioration of the nervous system, but the consequent loss of function may be considerably hastened by acute disease, such as stroke. In astronauts, sensory and motor relationships are altered soon after liftoff, without apparent anatomical or physiological compromise although "deconditioning" accompanies prolonged exposure to microgravity. As in the older person, such deconditioning is marked by homeostatic changes, including those related to the cardiovascular and musculoskeletal systems. Central to these changes and adaptations are neural events underlying vestibular function, vision, proprioception, and the integration of sensorimotor function. In the weightless environment of space, the vestibular otolithic receptors and the tactile proprioceptors no longer signal changes in body orientation as they do on earth. Central motor programs for the reinterpretation of sensory inputs and coordination of muscle actions must undergo adaptation. It is hypothesized that the rearrangement and mismatch of sensory cues gives rise to the syndrome of space motion sickness, to which the body gradually adapts.

The NIA and NASA convened a Workshop on Sensorimotor Integration and Disintegration to identify biomedical topics in sensorimotor integration and disintegration relevant to aging populations on Earth and to life in space under the unique conditions of microgravity. The research opportunities and directions, particularly as they relate to spatial

orientation, balance, and sensorimotor coordination, identified at this workshop form the basis for this program announcement. A copy of the report of this workshop can be obtained by contacting one of the program officials listed under INQUIRIES.

Research Goals and Scope

The NIA, NIDCD, NINDS, and NASA encourage submission of applications for research related to the mechanisms of sensorimotor adaptation and coordination, particularly in aging and in the microgravity conditions of space flight. Possible areas of research include, but are not limited to:

- o Development of new indices of sensorimotor adaptation.
- o Neural circuits and mechanisms subserving sensorimotor adaptation and learning in three-dimensional coordinate systems, including age-related changes.
- o CNS mechanisms contributing to the formation of a gravito-inertial frame of reference for cognitive activities and spatially directed motor tasks.
- o Neural and cognitive mechanisms underlying the transformation of extrinsic frames of reference into internal reference frames involved in coordination of volitional and reflexive movements of the joints, torso, head, neck, and eyes, such as reaching movements and eye-head gaze movements.
- o Strategies employed adaptively for the maintenance of spatial orientation with the loss or degradation of sensory inputs across the life-span.
- o Biomechanical and cognitive strategies used adaptively in spatially directed tasks, particularly with aging.
- o CNS mechanisms underlying the changes in multisensory and sensorimotor integration that accompany aging and exposure to altered gravito-inertial fields.
- o Adaptive change in the vestibulo-ocular reflex and/or visual-vestibulo-ocular functions as models for understanding motor learning and plasticity within the central nervous system.
- o Adaptive change in the vestibulospinal and postural reflexes.
- o The roles of interventions and prior experience in triggering compensation for the loss of sensorimotor functions.
- o Effect of time course, e.g., sudden onset vs. slow insidious onset, on the mechanisms underlying sensory adaptation to motor and environmental alterations.

While all research solicited in this program announcement will be conducted on Earth, NASA will provide access to special facilities in which various aspects of the real or perceived acceleration environment may be examined in ways not readily available to most researchers. Applicants are strongly encouraged to incorporate the utilization of NASA research facilities and resources and the collaboration with NASA scientists in their research plans. For more information contact the NASA program official. A brief listing of available facilities and the appropriate contact person(s) at each facility is available. NASA will contribute the costs associated with utilizing these facilities at no charge to the grantee.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 9, 1994 (FR 59 11146-11151) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit.

Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The title and number of this program announcement must be typed in Section 2a on the face page of the application.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit in accordance with the standard NIH peer review procedures. Following scientific-technical review, including responsiveness to the objectives of this program announcement, the applications will receive a second-level review by the appropriate national advisory council.

The following criteria will be used in evaluating applications submitted in response to this announcement:

- o Scientific and technical merit, significance, and originality of the proposed research;
- o Appropriateness and adequacy of the experimental approach and methodology to be used;
- o Qualifications of the principal investigator and staff in the area of research, and the principal investigator's prior research experience and record;
- o Adequacy of the available facilities.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that Institute or Center. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review;
- o Availability of funds;
- o Program balance among research areas of the announcement.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Direct inquiries regarding programmatic issues to:

Deborah Claman, Ph.D.
Neuroscience and Neuropsychology of Aging Program
National Institute on Aging
Gateway Building, Suite 3C307
Bethesda, MD 20892
Telephone: (301) 496-9350

Daniel Sklare, Ph.D.
Division of Communication Sciences and Disorders
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Room 400-C
Bethesda, MD 20892
Telephone: (301) 496-1804

William J. Heetderks, M.D., Ph.D.
Division of Fundamental Neurosciences
National Institute of Neurological Disorders and Stroke
Federal Building, Room 9C02
Bethesda, MD 20892
Telephone: (301) 496-5745

Victor Schneider, M.D.
Life and Biomedical Sciences and Applications Division
National Aeronautics and Space Administration
300 E Street, S.W., Code UL
Washington, DC 20546
Telephone: (202) 358-2359

Direct inquiries regarding fiscal matters to:

Vicki Maurer
Grants and Contracts Management Office
National Institute on Aging
Gateway Building, Suite 2N212
Bethesda, MD 20892
Telephone: (301) 496-1472

Sharon Hunt
Division of Extramural Activities
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Room 400D
6120 Executive Boulevard
Rockville, MD 20892
Telephone: (301) 402-0909

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.866 and No. 93.173. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ERRATA

MINORITY HIGH SCHOOL STUDENT RESEARCH APPRENTICE PROGRAM

NIH GUIDE, Volume 23, Number 28, July 29, 1994

PA NUMBER: PAR-94-081

P.T. 44; K.W. 0720005, 0502000

National Center for Research Resources

Application Receipt Date: October 18, 1994

The mechanism of support for PAR-94-081, which was published in the NIH Guide for Grants and Contracts, Vol. 22, No. 26, July 15, 1994, was incorrectly identified. The correct mechanism should read:

Minority High School Student Research Apprentice Program (S03).

INQUIRIES

Direct inquiries regarding programmatic issues to:

Marjorie A. Tingle, Ph.D.
Biomedical Research Support Program
National Center for Research Resources
Westwood Building, Room 10A-11
Bethesda, MD 20982
Telephone: (301) 594-7947

NATIONAL HUMAN SUBJECT PROTECTIONS WORKSHOPS

NIH GUIDE, Volume 23, Number 28, July 29, 1994

P.T. 42; K.W. 0783005

National Institutes of Health
Food and Drug Administration

The correct contact for the Human Subject Protections Workshop, which was published in the NIH Guide for Grants and Contracts, Vol. 23, No. 26, July 15, 1994; is as follows:

Office of Research
University at Buffalo
State University of New York
314 Crofts Hall
Buffalo, NY 14260-1234
Telephone: (716) 645-2018

INQUIRIES

For further information regarding these workshops or future NIH/FDA National Human Subject Protections Workshops, contact:

Ms. Darlene M. Ross
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 5B63
Bethesda, MD 20892
Telephone: (301) 496-8101

****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

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Bethesda, MD 20816



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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 29
August 5, 1994

RICHARD W HURRY

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S1350E

929 WILD FOREST DRIVE
GAITHERSBURG MD 20879 3209

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ERRATA

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ATTENTION: The new mailing list for the NIH Guide will be activated in September. Until then, the existing mailing list will be maintained. See INTENT TO MODIFY (NIH Guide, Vol. 23, No. 23, June 17, 1994) for additional information.

This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

THE PUBLIC HEALTH SERVICE (PHS) STRONGLY ENCOURAGES ALL GRANT RECIPIENTS TO PROVIDE A SMOKE-FREE WORKPLACE AND PROMOTE THE NON-USE OF ALL TOBACCO PRODUCTS. THIS IS CONSISTENT WITH THE PHS MISSION TO PROTECT AND ADVANCE THE PHYSICAL AND MENTAL HEALTH OF THE AMERICAN PEOPLE.

INNOVATIVE VENTRICULAR ASSIST SYSTEM

NIH GUIDE, Volume 23, Number 29, August 5, 1994

RFP AVAILABLE: NHLBI-HV-94-25

P.T. 34; K.W. 0706040, 0740035, 0705015

National Heart, Lung, and Blood Institute

The Bioengineering Section, Heart Program, Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute (NHLBI) has an interest in encouraging innovation in the development of totally implantable ventricular assist systems that are designed to achieve at least a five-year lifetime with 90 percent reliability. It is anticipated that the proposed systems will incorporate the latest advances in our understanding of circulatory support requirements, materials science, physics and bioengineering, biocompatibility, quality control, and manufacturing. It is expected that this five-year research and development program will be a multi-disciplinary effort and that offerors will include in their proposals theoretical bases for new and improved concepts; mathematical, computer, and physiological modeling; in vitro and animal testing of prototype systems; human fitting studies; evaluation of the biocompatibility of candidate materials; system monitoring; device maintenance; device replacement; environmental issues; and quality control. This solicitation is not intended to support formal device readiness testing nor is it intended to support human subject experimentation. However, the outcome of this program should be the availability of one or more ventricular assist systems that may be considered for future clinical studies. Four to six awards are anticipated. These incrementally funded contracts will be awarded for five years. This is not a Request for Proposals (RFP). RFP NHLBI-HV-94-25 will be released on or about August 3, 1994, with proposals due December 2, 1994.

INQUIRIES

Written requests must include three self-addressed mailing labels and cite RFP NHLBI-HV-94-25. FAX requests will be accepted. Requests for copies of the RFP are to be sent to:

Sharon M. Kraft
Contracts Operations Branch
National Heart, Lung, and Blood Institute
7550 Wisconsin Avenue MSC 9070
Federal Building, Room 4C04
Bethesda, MD 20892-9070
FAX: (301) 496-9501

SYNTHESIS AND TESTING OF NEW ANTIPROGESTATIONAL AGENTS

NIH GUIDE, Volume 23, Number 29, August 5, 1994

RFP AVAILABLE: NICHD-CD-94-13

P.T. 34; K.W. 1003006, 1003012, 0750020

National Institute of Child Health and Human Development

The Contraceptive Development Branch of the Center for Population Research, National Institute for Child Health and Human Development (NICHD) has a requirement for the synthesis and testing of antiprogesterone agents as postcoital antifertility agents. The goals of this acquisition are to design, synthesize, and test antiprogesterone agents that are at least ten-fold more potent orally than mifepristone in standard assays for antiprogesterone activity in laboratory animals. The selected prototypes for further structural modification may be mifepristone or other leads that have demonstrated oral activity. Such antagonists should, desirably, also have minimal hormonal and other antihormonal activities for use as contraceptive agents. Such antiprogesterone agents must also be devoid of effects on central nervous and cardiovascular systems. The Government will carry out in vivo biological assays required to establish the antiprogesterone activity of compounds submitted to the Contraceptive Development Branch under the auspices of this acquisition. Offerors must undertake standard in vitro progesterone and glucocorticoid binding assays on all the newly synthesized compounds in house or through subcontracting. Specifically excluded from consideration are (a) inhibitors of progesterone biosynthesis, and (b) estrogens. Organizations must have adequate facilities and capabilities to carry out the proposed synthetic chemical program and in vitro binding assays as mentioned above. The Government estimates the effort to be approximately 4.9 technical person-years annually. The principal investigator must be a synthetic organic and/or medicinal chemist with a Ph.D. degree, who will devote approximately 25 percent of her/his time to the project and must have five years of experience in drug synthesis. All responsible sources may submit a proposal that will be considered by the agency. It is anticipated that four cost-reimbursement incrementally funded type contracts will be awarded as a result of the request for proposals (RFP) for a period of 36 months, beginning June 1, 1995. This announcement is not an RFP. RFP NICHD-CD-94-13 will be available on or about August 19, 1994. Proposals will be due approximately 120 days thereafter.

INQUIRIES

Requests for copies of the RFP must cite the RFP number and be addressed to:

Paul J. Duska
Office of Grants and Contracts
National Institute of Child Health and Human Development
6100 Building, Room 7A07
Bethesda, MD 20892
FAX: (301) 402-3676

RFA AVAILABLE: HL-94-018

P.T. 44, FF; K.W. 0720005, 0715040, 0715032, 0715165

National Heart, Lung, and Blood Institute

Application Receipt Date: October 20, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACTS LISTED IN "INQUIRIES" BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Heart, Lung, and Blood Institute (NHLBI) invites grant applications for research training and career development programs directed at developing the research capabilities of minority individuals in areas relevant to cardiovascular, pulmonary, and hematologic diseases and resources. The specific minority research training and development programs encompassed under this RFA include: (1) the Minority Institutional Research Training program; (2) the Minority School Faculty Development Award program; (3) the Short-Term Training for Minority Students program; and, (4) the Research Development Award for Minority Faculty program. The purpose of these programs is to encourage the enhancement of research skills by minority individuals and to increase the number of minority individuals involved in research endeavors in the areas of interest to the NHLBI.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, NHLBI Minority Training and Development Programs, is related to the priority area of heart disease and stroke. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Awards for the programs described in this RFA will be made to domestic U.S. institutions or organizations, including minority institutions, engaged in health related-research in areas related to heart, lung, or blood disorders. Candidates for the career development awards and trainees appointed to the training programs must be either citizens or noncitizen nationals of the United States or have been lawfully admitted to the United States for permanent residence. Individuals on temporary or student visas are not eligible.

MECHANISMS OF SUPPORT

The mechanisms of support will be the National Institutes of Health (NIH) Institutional National Research Service Award (NRSA) (T32), Short-Term Training grant (T35), and Career Development Award (K14). Responsibility for the planning, direction, and execution of the proposed training and career development programs will be solely that of the applicant. The total project period for an application in response to this RFA may not exceed five years. The anticipated award date is May 1, 1995. Funding beyond the first year of the grant is contingent upon satisfactory progress during the preceding year and the availability of funds. Indirect costs will be awarded based on eight percent of total direct costs exclusive of equipment and tuition and fees.

FUNDS AVAILABLE

The estimated funds (total costs) available for the first year of support for the entire program is expected to approximate \$2 million in fiscal year 1995. The number of awards is estimated to be two awards for Minority Institutional Research Training Program, three awards for the Minority School Faculty Development Award Program, 10 awards for the Short-Term Training for Minority Students Program, and 12 awards for the Research Development Award for Minority Faculty. The actual amounts for the specific mechanisms may vary, depending on the response to the RFA and availability of funds. Funding beyond the first and subsequent years of the grant will be contingent upon satisfactory progress during the preceding years and availability of funds.

RESEARCH OBJECTIVES

The present RFA is designed to offer research training and career development opportunities for minority individuals and encourage their participation in cardiovascular, pulmonary, and hematologic research. The Minority Research Training and Career Development programs are intended to:

- o Bolster the participation and research capabilities of minority individuals in research areas relevant to heart, lung, and blood diseases.
- o Increase the pool of qualified minority investigators pursuing research in heart, blood vessel, lung, and blood disease and transfusion medicine.

See the RFA for specific objectives for the individual minority training and development programs.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301-594-7248). Applications must be received by October 20, 1994. The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2a of the face page of the application form and the YES box must be marked. Guidelines and supplemental instructions for each of the specific programs may be obtained from NHLBI staff listed under INQUIRIES.

REVIEW CONSIDERATIONS

All applications will be reviewed for scientific and technical merit by the Research Training Review Committee of the Division of Extramural Affairs, NHLBI, followed by a second level review by the National Heart, Lung, and Blood Advisory Council.

The general review criteria for applications submitted under this RFA are those considered when assessing the merit of career development applications, including the Minority School Faculty Development Award and the Research Development Award for Minority Faculty, or institutional National Research Service Award research training applications, including the Minority Institutional Research Training program and the Short-Term Training for Minority Students program.

AWARD CRITERIA

Funding decisions will be made on the basis of technical merit of the application as determined by peer review, availability of funds, and program balance among the research areas of the RFA.

INQUIRIES

Written and telephone requests for this RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA, program guidelines, and supplemental instructions, and inquiries regarding programmatic issues to:

John Fakunding, Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 3C04
Bethesda, MD 20892
Telephone: (301) 496-1724

Direct inquiries regarding review issues and mail two copies of the application to:

Kathryn Ballard, Ph.D.
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 550
Bethesda, MD 20892
Telephone: (301) 594-7450

Direct inquiries regarding fiscal matters to:

Jane Davis
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A15C
Bethesda, MD 20892
Telephone: (301) 594-7436

Schedule

Application Receipt Date: October 20, 1994
Scientific Review Date: December 1994
Advisory Council Date: February 9-10, 1995
Earliest Award Date: May 1, 1995

AUTHORITY AND REGULATION

This program is described in the Catalog of Federal Domestic Assistance Numbers 93.837, 93.838, and 93.839. Awards are made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 288 and administered under PHS grants policies and Federal Regulations at 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

RFA AVAILABLE: CA-94-028

P.T. 34; K.W. 0785055, 0715035, 0760002

National Cancer Institute
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Environmental Health Sciences

Letter of Intent Receipt Date: October 17, 1994

Application Receipt Date: November 23, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Cancer Etiology, National Cancer Institute (NCI); Division of Kidney, Urologic, and Hematologic Diseases, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK); and Chemical Exposures and Molecular Biology Branch, National Institute of Environmental Health Sciences (NIEHS) invite investigator-initiated research grant applications for molecular epidemiologic studies to further the understanding of prostate cancer etiology. A major emphasis of this RFA is to stimulate the use of biochemical and molecular markers for identifying and assessing risk factors of prostate cancer, which could lead to effective prevention strategies.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Molecular Epidemiology of Prostate Carcinogenesis, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Domestic and foreign, non-profit and for-profit, public and private institutions, and units of local, State, and Federal governments are eligible to apply. Foreign institutions and organizations are not eligible for the First Independent Research Support and Transition (FIRST) (R29) awards. Minority and women investigators are encouraged to apply.

MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health (NIH) individual research project grants (R01), FIRST awards (R29), and competing supplements (S01) to current R01 awards. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA may not exceed five years. The earliest award date is July 1, 1995.

Because the nature and scope of the research proposed may vary, it is anticipated that the size of an average award will vary also ranging from \$150,000 to \$500,000 in total costs per year. If direct costs exceed \$500,000 in any year, the funded study may be considered for an award as a cooperative agreement (U01) (refer to NIH Guide, Vol. 22, Nos. 43 and 45, November 26, and December 17, 1993). Total direct cost award for the five-year R29 grant period may not exceed \$350,000 and the direct cost award in any R29 budget period should not exceed \$100,000.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary NIH peer review procedure.

FUNDS AVAILABLE

Approximately \$3.75 million (\$2,000,000 from NCI, up to \$1,000,000 from NIDDK, and \$750,000 from NIEHS) in total costs per year for five years will be committed to specifically fund applications which are submitted in response to this RFA. It is anticipated that 8 to 12 awards will be made. Should the NCI, NIDDK, and NIEHS determine that there are sufficient continuing program needs, recipients of awards under this RFA will be invited to submit competing continuation awards.

RESEARCH OBJECTIVES

The purpose of this RFA is to stimulate innovative molecular epidemiologic research into the origins of prostate cancer, including the biological basis for the striking increase in prostate cancer incidence with age. The types of studies could include, but are not limited to: characterization and validation of biomarkers relevant to prostate carcinogenesis including consideration of variables such as ethnicity, genetic predisposition, diet, and lifestyle; assessment of sex hormonal profiles in body fluids; identification of premalignant lesions; elucidation of the natural history of invasive cancer or progressive stages of the carcinogenic process; exploration of timing of environmental exposures relevant to prostate cancer development; evaluation of micronutrients, macronutrients, xenobiotics and their interactions with hormones and hereditary factors; and clarification of the possible relationships of benign prostatic hyperplasia or chronic prostatitis to prostate cancer.

SPECIAL REQUIREMENTS

Successful grant awardees under this RFA are strongly encouraged to participate in two, one-day program meetings to be held in Bethesda, Maryland during the second and fifth years of the grant. NIH program staff will coordinate the meetings, which will provide the opportunity for investigators to discuss their work in progress and to consider methodological and scientific issues. The respondents may request sufficient funds within the budget to accommodate expenses for one to two participants at each meeting.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are encouraged to submit, by October 17, 1994, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator, the names of other key personnel, participating institutions, and estimated amount of direct costs if anticipated to exceed \$500,000 for any year. Potential applicants for research of this magnitude are encouraged to contact the NCI prior to making detailed plans or submitting their applications. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. The letter of intent is to be sent to Dr. Kumiko Iwamoto at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be received by November 23, 1994, on form PHS 398 (rev. 9/91), available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248.

REVIEW CONSIDERATIONS

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group followed by a second level of review by the National Cancer Advisory Board, the National Advisory Council for Diabetes and Digestive and Kidney Diseases, and the National Advisory Environmental Health Sciences Council.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Dr. Kumiko Iwamoto
Epidemiology and Biostatistics Program
National Cancer Institute
6130 Executive Boulevard, Room 535
Bethesda, MD 20892
Telephone: (301) 496-9600
FAX: (301) 402-4279

Direct inquiries regarding fiscal matters to:

Ms. Theresa A. Mercogliano
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Suite 242
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 243
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.393 and 93.894. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

STENT PATENCY AND STENOSIS IN TIPS

NIH GUIDE, Volume 23, Number 29, August 5, 1994

PA NUMBER: PA-94-090

P.T. 34; K.W. 0715040, 0715115

National Institute of Diabetes and Digestive and Kidney Diseases

PURPOSE

The purpose of this Program Announcement (PA) is to encourage research on the nonsurgical Transjugular Intrahepatic Porto-Systemic Shunt (TIPS) procedure in the areas of stent patency and stent stenosis. The TIPS procedure has recently become available for the treatment of portal hypertension, variceal bleeding, and ascites. At present the long term effectiveness of TIPS is related to shunt patency and stent stenosis. Studies related to technological advances that improve long term patency as well as studies on stent occlusion and fibrosis are encouraged.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000" a PHS-led national activity for setting priority areas. This PA, Stent Patency and Stenosis in TIPS, is related to the priority area of chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research and Transition (FIRST) (R29) awards. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The support for this program announcement will be through the NIH research project grant (R01) award and the FIRST (R29) award. Applications seeking support of technological improvements of stents may consider the Small Business Innovation Research (SBIR) program (R43) or the Small Business Technology Transfer (STTR) program (R41) of the NIH, in which the NIDDK participates. For-profit applicants for the SBIR and STTR programs must qualify as a small business concern in accordance with the definition given in the latest edition of the OMNIBUS SOLICITATION OF THE PUBLIC HEALTH SERVICE FOR SMALL BUSINESS INNOVATION RESEARCH (SBIR) GRANT AND COOPERATIVE AGREEMENT APPLICATIONS, available from: MTL, Inc., 13687 Baltimore Avenue, Laurel, MD 20707-5096, telephone (301) 206-9385; FAX (301) 206-9722, Internet address: a2y@cu.nih.gov.

RESEARCH OBJECTIVES

Transjugular intrahepatic porto-systemic shunt has recently become available for the treatment of portal hypertension, variceal bleeding and ascites. The TIPS procedure is highly effective in reducing portal pressure and is thus beneficial in the medical management of patients with acute variceal hemorrhage. However, TIPS is an invasive procedure and is associated with several potential complications. These complications can be categorized according to those relating to transhepatic needle puncture, transvenous access to the portal vein, portal venous cannulation, portosystemic shunting and the stent. At present, long term efficacy is related to shunt patency. For the first year after undergoing the procedure, delayed stenosis or occlusion of the shunt has been reported in 33 to 66 percent of the patients. The pathological process results from either hyperplasia and collagen deposition within the stent or the narrowing of the vascular lumen at the portal venous end of the TIPS stent. New technologies or advances in existing technologies to develop stent materials should be directed to improve long term patency. Further studies to develop research should be directed at elucidating methods to reduce fibrosis and or occlusion of the stent. The latter studies could focus on the role of anticoagulation agents, anti-collagen or fibrotic agents, or anti-inflammatory regimens, such as cytokines, in the maintenance of stent patency. Thus, applications are requested that would improve the technology involving stent patency.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). Applications will be accepted at the regular application deadlines as indicated in the application kit. The receipt dates for applications for AIDS-related research are found in the PHS 398 instructions.

Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institute of Health, Westwood Building, Room 449, Bethesda, MD 20992, telephone 301/594-7248. The title and number of this program announcement must be typed in Section 2a on the face page of the application.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institute of Health
Westwood Building Room 240
Bethesda, MD 20892**

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director or a Principal Investigator must be included with the application.

FIRST Award applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines and will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by an appropriate National Advisory Council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Thomas F. Kresina, Ph.D.
Division of Digestive Diseases and Nutrition
National Institute of Digestive Diseases and Kidney Diseases
Westwood Building, Room 3A17
45 Center Drive MSC 6600
Bethesda, MD 20892-6600
Telephone: (301) 594-7578

Direct inquiries regarding fiscal matters to:

Ms. Paulette Badman
Grants Management Branch
National Institute of Digestive Diseases and Kidney Diseases
Westwood Building, Room 639
45 Center Drive MSC 6600
Bethesda, MD 20892-6600
Telephone: (301) 594-7543

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.848. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78- 410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

PA NUMBER: PA-94-091

P.T. 34; K.W. 0775005, 0410001

National Institute on Deafness and Other Communication Disorders

PURPOSE

The understanding of the mechanisms by which deaf and hearing individuals acquire and use a manual communication system is limited. Research is needed to determine optimal conditions for such learning, prerequisite abilities for successful acquisition and use of a manual system, as well as the interindividual variations of acquisition of manual communication. The National Institute on Deafness and Other Communication Disorders (NIDCD) encourages applications for the support of studies of the sensory, perceptual, cognitive, neural, and molecular mechanisms underlying acquisition and use of a signed language.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement (PA), Mechanisms Underlying Sign Language Acquisition and Use, is related to the priority area of diabetes and chronic disabling conditions and, special population objectives. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-11474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-11473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Applications from minority individuals, women, and individuals with disabilities are encouraged.

MECHANISM OF SUPPORT

The support mechanisms for grants in this area will be the individual investigator-initiated research project grant (R01) and the FIRST (R29) award.

RESEARCH OBJECTIVES

A large proportion of individuals born deaf or who lose their hearing before they acquire spoken language use a form of sign language as their primary mode of communication, either English-language based signing systems or American Sign Language (ASL). Research is needed to increase the understanding of the processes that underlie the acquisition and use of a manual communication system by deaf individuals. Studies concerning the processes and bases of sign language acquisition and use may identify the optimal conditions for learning a manual sign system. This will lead to the development of a model of language that can address the relationship of spoken and signed languages and may also help delineate new methods of successfully introducing and using English with deaf children.

Acquisition and processing of signed languages. Language acquisition for deaf children with signing deaf parents typically involves use of American Sign Language (ASL). Previous research, although limited, has indicated that in those individuals exposed to ASL from birth, linguistic competence, on-line sentence processing and underlying neural mechanisms for language may be similar to those found in hearing users of native spoken languages. Additional studies are needed of cognitive, motor, neural, and molecular processes involved in acquisition of ASL among deaf children of deaf parents. A better understanding also is needed of typical patterns of sign language development, and the processes involved in perception and production of sign language in deaf children of hearing parents. Recent evidence suggests that increasing numbers of hearing parents are using sign communication with their deaf children. They commonly use English-based signing, but there is a growing interest in the use of ASL by hearing parents and siblings. There is also a need for additional studies of patterns of acquisition and the cognitive, motor, neural, and molecular processes involved in signing. Recent research findings, concerning the acquisition of ASL by deaf children of hearing parents at various ages beyond infancy, indicate that there is a critical period for the acquisition of ASL, just as there is for the acquisition of spoken languages by hearing individuals. Competency in and efficiency of processing ASL appears to be related to age of exposure to ASL, with a decline in competency and efficiency and possible changes in neural organization for later learners. A full explanation of this phenomenon awaits further investigation.

Cognitive, perceptual, and motor processes, and psychosocial issues related to sign language acquisition and use. Acquisition of the ability to employ a signed language depends on the development of a number of interrelated cognitive and linguistic abilities that contribute to the perception and production of sign language. In addition, the nonlinguistic/cognitive outcomes in deaf children exposed to various kinds of sign language are undocumented and warrant investigation. The relation of cognitive and psychosocial development to sign language acquisition and use requires further investigation. Sign language production makes use of space and movement; thus the perception of sign language requires the processing of complex arrays of dynamic motion. Investigations are needed of sign language perception, particularly the processing of motion and form and how such visual-dynamic information is processed linguistically. Comparison of the processes of spoken language perception and signed language perception in hearing and deaf individuals provides a unique means of determining those aspects of language that are independent of the modality (signed or spoken) of communication.

Neural underpinnings of sign language acquisition and use. The interface of sign language acquisition to other biological phenomena is important to our understanding of brain-behavior relationships. Electrophysiologic findings indicate that, in spite of the very different input/output systems employed, the same or similar areas in the left

hemisphere of the brain are involved in language tasks in native ASL signers as in speakers of English. However, studies of this type, examining the organization of the brain and its relation to sign language acquisition and use, are limited. Studies of brain mapping of sign language function are needed, as are continued investigations of differences and similarities in the way the brain processes spoken and signed languages. Questions remain concerning the ways in which cortical organization may be influenced by age of acquisition and by early perceptual and linguistic experience.

Examples of issues to be addressed in applications submitted in response to this Program Announcement include, but are not limited to, the following:

- o The acquisition of ASL or other signing systems in children exposed to these languages from birth as well as in children whose access to a first natural language is delayed or incomplete;
- o The relation between cognitive and psychosocial development and the acquisition of ASL in deaf children of deaf parents and in deaf children of hearing parents;
- o The relation of infants' early acquisition of sign language phonology, assessed through tests of sign perception, to the acquisition of other levels of a signed language, such as the acquisition of signs (lexicon), sign meanings (semantics) and grammatical constructions (syntax);
- o The underlying perceptual and motor processes in sign language, for example, basic and higher level processes underlying the perception and use of space, form and movement in sign language;
- o The nature of parallel processing of simultaneous visual and auditory information in deaf children and adults;
- o Identification and characterization of the neural systems that underlie the representation, perception and production of signed languages in both adults and children using, when appropriate, techniques such as measuring event-related potentials and imaging technology;
- o The specialization of the cerebral hemispheres for language and other types of cognitive processing in deaf individuals, including the ways in which the neural organization and function of the basic sensory systems may be changed by deafness and/or by acquisition of sign language;
- o Critical periods for the natural acquisition of signed languages, and the effects of delayed exposure to spoken or signed language on the development of linguistic competence and cognitive and academic abilities.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 18, 1994 (FR 59 14508-14513) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit. These kits are available from most institutional offices of sponsored research; the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and the NIDCD Program Administrator listed under INQUIRIES. The title and number of the program announcement must be typed in Section 2a on the face page of the application.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be reviewed for scientific and technical merit by an appropriate Initial Review Group within the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following scientific/technical review, the applications will receive a second-level review by the appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that ICD. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review.
- o Availability of funds.
- o Program priorities among research areas of the announcement.

INQUIRIES

Written and telephone inquiries concerning this PA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Judith A. Cooper, Ph.D.
Division of Communication Sciences and Disorders
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Room 400-C
6120 Executive Boulevard
Rockville, MD 20892
Telephone: (301) 496-5061
FAX: (301) 402-6251

Direct inquiries regarding fiscal matters to:

Sharon Hunt
Grants Management Office
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Room 400-B
6120 Executive Boulevard
Rockville, MD 20892
Telephone: (301) 402-0909

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.173. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NEW INSIGHTS INTO CHRONIC FATIGUE SYNDROME

NIH GUIDE, Volume 23, Number 29, August 5, 1994

PA NUMBER: PA-94-092

P.T. 34; K.W. 0715043

National Institute of Allergy and Infectious Diseases
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Mental Health

PURPOSE

The National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), and National Institute of Mental Health (NIMH) invite investigator-initiated research grant applications to support research on the etiology, natural history, and pathogenesis of chronic fatigue syndrome (CFS).

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, New Insights into Chronic Fatigue Syndrome, is related to the priority area of chronic disabling diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-0325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards.

MECHANISM OF SUPPORT

Traditional research project grant (R01) and FIRST award (R29) applications may be submitted in response to this program announcement. The R01 mechanism can be used to support small studies. Funds and time requested should be appropriate for the research proposed.

RESEARCH OBJECTIVES

Background

Chronic fatigue syndrome (CFS) is a multisystem syndrome thought to be triggered by acute infectious illness and characterized by months of debilitating fatigue frequently associated with myalgia, headache, sore throat, low grade fever, cognitive complaints, gastrointestinal symptoms, and tender lymph nodes. There have been reports of immunologic and, more recently, neuroendocrine parameters that differ in CFS patients as a group compared to healthy controls. However, no single marker has been identified that can be used to diagnose the syndrome. CFS is diagnosed three to four times more frequently in women than in men and about 10 times more often in white Americans than in other American population groups. The cause and pathogenic mechanisms of the illness are unknown.

Research Objectives and Experimental Approaches

Well-designed studies are needed to provide a better understanding of CFS and to develop diagnostic and intervention strategies. Studies should include appropriate sample sizes and test biologically rational hypotheses concerning etiology, natural history or pathogenesis of the syndrome. Applications for small studies that explore new ideas are also encouraged and could provide the basis for submission of a subsequent larger grant application.

Clinical epidemiologic studies may identify factors that affect prognosis or that are associated with susceptibility, including immunogenetic, behavioral, environmental, and psychosocial factors. Several observations reported in the literature merit further study to determine their biologic and/or epidemiologic basis, generalizability and/or role in CFS. These include, but are not limited to:

- o lymphocyte patterns suggestive of immune activation (e.g., alterations in T-cell subsets number and function, altered cytokine levels and function)
- o low levels of cortisol and corticotropin-releasing hormone in CFS patients in the absence of documented adrenal-hypothalamic axis dysfunction attributable to other causes
- o increased frequency of sleep disturbances (hypersomnia or insomnia)
- o overlapping symptomatology with fibromyalgia
- o low tolerance to physical exertion manifested by prolonged generalized fatigue after very moderate exercise
- o demographic risk factors (gender, age, race, socioeconomic class)
- o reactivation of latent viruses (e.g., use of sensitive and specific assays to measure viral reactivation in carefully defined and controlled specimens)
- o increased frequency of psychiatric diagnoses in CFS patients (except those that would exclude an individual from the CFS case definition)
- o increased frequency of atopy in CFS patients compared with the U.S. population as a whole
- o highly active lifestyle prior to onset of CFS

Multidisciplinary studies and collaboration among investigators with expertise in appropriate disciplines are encouraged. When investigators are at different institutions, individual R01 applications may include consortium arrangements.

Collaborative arrangements with on-going studies that provide patient populations, specimens and data are encouraged. Such arrangements should be clearly delineated in the application.

The methodologies and personnel involved in statistical/epidemiological analyses should be described in the application and evident in the study design. The hypothesis(es) to be tested should be clearly stated. The constructs and measurements to be used operationally to obtain statistically and biologically meaningful results should be clearly defined and enumerated.

The value of studies of patients or their specimens will be directly related to the care exercised in selection and initial characterization of cases and controls. A detailed description of case recruitment procedures, the criteria to be used for case definition and the manner in which the criteria are to be applied must be included. Similar care should be given to descriptions of enrollment of comparison groups. Investigators are encouraged to use the CFS case definition as initially presented in Holmes, et al. (Annals of Internal Medicine: 108, 387-389, 1988) and subsequently modified in Schluederberg, et al. (Annals of Internal Medicine: 117, 325-331, 1992) and in Fukuda, et al (in press). If other case definitions are proposed, they should be clearly defined and the rationale for their choice clearly delineated.

Parameter Measurements

Applications to estimate the frequency of physiological or behavioral variables or responses or to address other quantitative aspects in relevant populations should pay particular attention to sample sizes required to attain the degree of precision sought or needed for statistically and biologically meaningful results. The reliability and validity of markers chosen for measurement should be demonstrated. Applications attempting to examine interrelationships among two or more separate factors are encouraged to the extent that the types and numbers of subjects are sufficient for such comparisons.

The measurement of cellular phenotypes, cytokine activities and other immunological and viral markers are highly dependent on the assay system chosen and its execution. Thus, it is very important that applicants clearly define the methodologies to be used, the rationale for choosing that methodology and for validating results as well as methods of collection, processing, and storage of samples. When conflicting results have been reported in the literature,

applicants should provide possible explanations for such variability and indicate how their approach might resolve the issue.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the program staff or contact persons listed below. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted on the standard application deadlines as indicated in the application kit. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

Each application must be identified by checking "YES" on line 2a of the PHS face page, and the number and title of this announcement must be typed in section 2a.

FIRST (R29) applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The completed original and five legible, single-sided copies of the application must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the Center as a resource for conducting the proposed research. If so, a letter of agreement from the GCRC Program Director must be included in the application material.

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following scientific/technical review, the applications will receive secondary review by the appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other favorably recommended applications assigned to that ICD. The following will be considered when making funding decisions: quality of the proposed project as determined by peer review, program balance among research areas of the announcement, availability of funds.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues from potential applicants is welcome. Direct inquiries regarding programmatic issues to:

Susan Spring, Ph.D.
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3A14
6003 Executive Boulevard MSC 7630
Bethesda, MD 20892-7630
Telephone: (301) 496-7453
FAX: (301) 496-8030

Susana A. Serrate-Sztejn, Ph.D.
Arthritis Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 405
Bethesda, MD 20892
Telephone: (301) 594-9953
FAX: (301) 594-9673

Fred Altman, Ph.D.
Basic Prevention and Behavioral Medicine Research Branch
National Institute of Mental Health
Parklawn Building, Room 11C06
Rockville, MD 20857
Telephone: (301) 443-4337
FAX: (301) 443-4822

Direct inquiries regarding fiscal matters to:

Ms. Victoria Putprush
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B35
6003 Executive Boulevard MSC 7610
Bethesda, MD 20892-7610
Telephone: (301) 496-7075
FAX: (301) 480-3780

Mr. Joseph L. Brown
Grants Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 722C
Bethesda, MD 20892
Telephone: (301) 594-9970
FAX: (301) 594-9950

Mr. Bruce Ringler
Grants Management Branch
National Institute of Mental Health
Parklawn Building, Room 7C08
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-3065

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.856, Microbiology and Infectious Disease Research, No. 93.846, Arthritis, Musculoskeletal, and Skin Diseases Research and No. 93.242, Mental Health Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grant policies and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ERRATA

NEUROENDOCRINOLOGY OF AGING

NIH GUIDE, Volume 23, Number 29, August 5, 1994

PA NUMBER: PA-94-087

P.T. 34; K.W. 0710010, 0785105

National Institute on Aging
National Institute of Diabetes and Digestive and Kidney Diseases

The following correction is issued for PA-94-087, which was published in the NIH Guide, Vol. 23, No. 28, July 29, 1994.

The second sentence under MECHANISM OF SUPPORT should read:

Foreign institutions are NOT eligible for FIRST (R29) awards.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Andrew A. Monjan, Ph.D., M.P.H.
Neuroscience and Neuropsychology of Aging Program
National Institute on Aging
Gateway Building, Suite 3C307
Bethesda, MD 20892
Telephone: (301) 496-9350
FAX: (301) 496-1494

****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

5333 Westbard Avenue
Bethesda, MD 20816



NIH GUIDE

For Grants and Contracts

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National Institutes of Health

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Building 31, Bethesda, Maryland 20892

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 30
August 12, 1994

RICHARD W MURRY

* 340189
S1350E

929 WILD FOREST DRIVE
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ATTENTION: The new mailing list for the NIH Guide will be activated in September. Until then, the existing mailing list will be maintained. See INTENT TO MODIFY (NIH Guide, Vol. 23, No. 23, June 17, 1994) for additional information.

This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

THE PUBLIC HEALTH SERVICE (PHS) STRONGLY ENCOURAGES ALL GRANT RECIPIENTS TO PROVIDE A SMOKE-FREE WORKPLACE AND PROMOTE THE NON-USE OF ALL TOBACCO PRODUCTS. THIS IS CONSISTENT WITH THE PHS MISSION TO PROTECT AND ADVANCE THE PHYSICAL AND MENTAL HEALTH OF THE AMERICAN PEOPLE.

FINAL FINDINGS OF SCIENTIFIC MISCONDUCT

NIH GUIDE, Volume 23, Number 30, August 12, 1994

P.T. 34; K.W. 1014004

Public Health Service

Notice is hereby given that the Office of Research Integrity (ORI) has made final findings of scientific misconduct in the following cases:

Anand Tewari, M.D., Stanford University. The Division of Research Investigations (DRI) of the Office of Research Integrity (ORI) conducted an investigation into possible scientific misconduct on the part of Dr. Tewari while a postdoctoral fellow in the Department of Surgery, Stanford University School of Medicine. ORI concluded that Dr. Tewari committed scientific misconduct in clinical research supported by an NIH grant by fabricating ophthalmologic examination results; fabricating and falsifying blood gas data; fabricating and falsifying values for glycerol determinations; falsifying standard errors and including fabricated data on platelet counts in a published article, "Effects of interleukin-1 on platelet counts" (The Lancet 336:712-714 (1990)), and related abstracts; and providing to his supervisors summaries of data that included falsified and fabricated data which were used in a PHS grant application. The published article containing the falsified and fabricated data was retracted on August 22, 1992. The Lancet 340:496. Dr. Tewari accepted the ORI findings and agreed to a Voluntary Exclusion and Settlement Agreement under which he may not apply for Federal grant or contract funds except for the non-research training or practice of clinical medicine, and may not serve on PHS advisory committees, boards, or peer review groups for a five-year period beginning March 1, 1994.

Annmari Surprenant, Ph.D., Glaxo Institute for Molecular Biology. An inquiry and investigation conducted by the Oregon Health Sciences University (OHSU) found that Annmarie Surprenant, Ph.D., had misrepresented her academic credentials in a grant application for Public Health Service (PHS) research funds. The OHSU found that Dr. Surprenant had falsely stated that she had earned an M.D. degree from the University of Illinois at Chicago in 1976. As a result of the OHSU investigation, Dr. Surprenant resigned from the OHSU faculty. During its oversight review of the OHSU report, the Office of Research Integrity (ORI) discovered that Dr. Surprenant had also falsely claimed to have earned an M.D. on two additional PHS research grant applications. Based upon the OHSU report, as well as the information obtained by ORI during its oversight review, ORI found that Dr. Surprenant engaged in scientific misconduct by falsely claiming to have earned an M.D. in three PHS research grant applications. Dr. Surprenant accepted the ORI finding and agreed to a Voluntary Exclusion and Settlement Agreement under which she will not apply for Federal grant or contract funds and will not serve on PHS advisory committees, boards, or peer review groups for a three-year period beginning June 8, 1994.

Mark S. Chagnon, Sc.D., Molecular BioQuest, Inc. A report of the Office of Research Integrity (ORI) of its investigation into allegations of possible scientific misconduct made against Mark S. Chagnon found that he engaged in scientific misconduct by misrepresenting his academic credentials in five research grant applications submitted to the National Institutes of Health. ORI found that Dr. Chagnon falsely claimed to have completed undergraduate and graduate studies in chemistry at the Massachusetts Institute of Technology (MIT), Lowell University (Lowell Institute of Technology) and Northeastern University. ORI also concluded that Dr. Chagnon falsely claimed to have earned an M.S. degree in organic chemistry from MIT. Although he neither admits nor denies the ORI finding of scientific misconduct, Dr. Chagnon has agreed to a Voluntary Exclusion and Settlement Agreement under which he will not apply for Federal grant or contract funds and will not serve on PHS advisory committees, boards, or peer review groups for a three-year period beginning June 28, 1994.

INQUIRIES

The Office of Research Integrity will continue to publish findings of scientific misconduct as further cases are closed. For further information, contact:

Director
Division of Research Investigations
Office of Research Integrity
5515 Security Lane, Suite 700
Rockville, MD 20852
Telephone: (301) 443-5330

ADDITION OF THE FEMALE CONDOM TO A PROSPECTIVE OBSERVATIONAL STUDY OF BARRIER CONTRACEPTION FOR PREVENTION OF SEXUALLY TRANSMITTED DISEASES

NIH GUIDE, Volume 23, Number 30, August 12, 1994

P.T. 34; K.W. 0715182, 0750020

National Institute of Child Health and Human Development

National Institute of Child Health and Human Development Contract Number N01-HD-1-3135 has been modified to expand the requirements in the amount of \$4,824,822 for the addition of the female condom to other contraceptive choices available in a study of barrier contraception for the prevention of sexually transmitted diseases among a group of high-risk women.

INQUIRIES

Inquiries regarding this notice may be directed to:

Charles W. Grewe
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Building, Room 7A07
6100 Executive Boulevard MSC 7510
Bethesda, MD 20892-7510

NATIONAL ANIMAL WELFARE EDUCATION WORKSHOPS

NIH GUIDE, Volume 23, Number 30, August 12, 1994

P.T. 42; K.W. 0201011, 1014003

National Institutes of Health

The National Institutes of Health, Office for Protection from Research Risks is continuing to sponsor workshops on implementing the Public Health Service Policy on Humane Care and Use of Laboratory Animals. Each of the workshops scheduled for Fiscal Year 1994 and 1995 will focus on a specific theme. The workshops are open to institutional administrators, members of Institutional Animal Care and Use Committees, laboratory animal veterinarians, investigators and other institutional staff who have responsibility for high-quality management of sound institutional animal care and use programs. Ample opportunities will be provided to exchange ideas and interests through question and answer sessions and informal discussions.

DATES: September 29-30, 1994

TOPIC: Use of Animals in Research and Alternatives

LOCATION: The Monteleone Hotel, New Orleans, LA

SPONSORS
Louisiana State University Medical Center
Xavier University of Louisiana

REGISTRATION
Ms. Lois Herbez
Louisiana State University Medical Center
1542 Tulane Avenue
New Orleans, LA 70112
Telephone: (504) 568-4198
FAX: (504) 568-4843

FEE: \$150

DESCRIPTION: The theme of the workshop will address various aspects of the use of animals in research and the role of animals and alternatives in research and education. The workshop will address such issues as: (1) Adequacy of Computer Searches; (2) NIH, USDA, FDA Alternatives Initiative; (3) Occupational Health - Implementation, Update and Biosafety Concerns; (4) Roles of Animals and Alternatives in Education.

DATES: December 1-2, 1994

TOPIC: New Frontiers in Surgery

LOCATION
Sheraton Charleston
170 Lockwood Drive
Charleston, SC 29403
Telephone: (803) 723-3000
FAX: (803) 723-3000

SPONSOR
Medical University of South Carolina

REGISTRATION
M. Michael Swindle, D.V.M.
MUSC/Comparative Medicine
171 Ashley Avenue
Charleston, SC 29425-2211
Telephone: (803) 792-3625
FAX: (803) 792-9067

FEE: \$150.00 (Before Nov 15, 1994) \$175.00 (After Nov 15, 1994)

DESCRIPTION: The Workshop will address ethics, protocol review and technical and training aspects related to new surgical and interventional technologies. Topics to be discussed in the program include xenographic procedures, fetal intervention, transgenic technologies, and use of biomaterials in orthopedic surgery.

DATES: January 12-13, 1995

TOPIC: Considerations For Use of Wild Vertebrates in Research

LOCATION
Westward Look Resort
245 Ina Road
Tucson, AZ 85704
Telephone: (602) 297-1151 or 1-800-722-2500
FAX: (602) 297-9023

SPONSORS
Northern Arizona University
University of Arizona Health Science Center

REGISTRATION
Dr. Terry May
Director of Research Administration
Northern Arizona University
P.O. Box 4130
Flagstaff, AZ 86011-4130
Telephone: (602) 523-6788
FAX: (602) 523-1075
E Mail: tam1@nauvax.ucc.nau.edu

Dr. Susan Sanders, Director
University of Arizona Animal Care
2205 E. Speedway Boulevard
Tucson, AZ 85719
Telephone: (602) 621-3454
FAX: (602) 621-3355

FEE: \$175 - Full Workshop \$70 - Daily Registration as Space Available

DESCRIPTION: This Workshop will focus on three general themes related to the inclusion of native vertebrates in research: (1) Federal and institutional policies and procedures as they relate to the responsibilities of the Institutional Animal Care and Use Committee (IACUC) in considering research on both captive and free-living wild vertebrates; (2) standards for the husbandry and housing of captive wild vertebrates; and (3) occupational health considerations with an emphasis on rodent-borne hantavirus.

DATES: March 12-14, 1995

TOPIC: Animal Care and Research: Challenges and Changes for the Institutional Animal Care and Use Committee

LOCATION
San Diego Princess
1404 West Vacation Road
San Diego, CA 92109-7994
Telephone: (619) 274-4630 or (1-800) 344-2626
FAX: (619) 581-5929

SPONSORS
Tufts University School of Veterinary Medicine
Public Responsibility in Medicine and Research

REGISTRATION
Ms. Danielle Demko
Public Responsibility in Medicine and Research
132 Boylston Street
Boston, MA 02116
Telephone: (617) 423-4112
FAX: (617) 423-1185

FEE: \$300

DESCRIPTION: The Workshop will focus on revisions to the Institutional Animal Care and Use Committee Guidebook; assessment and reduction of pain and distress in animal research; occupational health risks and biohazards; and a host of other regulatory and administrative issues that are central to the successful operation of laboratory animal care and research programs.

Immediately preceding the Tufts University School of Veterinary Medicine/NIH/OPRR Workshop, Applied Research Ethics National Association (ARENA) will sponsor its annual animal issues meeting on Sunday, March 12, also at the San Diego Princess.

INQUIRIES

For further information concerning these workshops and future NIH/OPRR Animal Welfare Education Workshops, contact:

Mrs. Roberta Sonneborn
Office of Protection from Research Risks
National Institutes of Health
Building 31, Room 5B63
Bethesda, MD 20892-2180
Telephone: (301) 496-7163
FAX: (301) 402-2803

NOTICES OF AVAILABILITY (RFPs AND RFAs)

DISTRIBUTION OF MOUSE MODELS FOR NEURAL TUBE DEFECTS

NIH GUIDE, Volume 23, Number 30, August 12, 1994

RFP AVAILABLE: NICHD-CRMC-95-07

P.T. 34; K.W. 0755020, 1002002, 1002030

National Institute of Child Health and Human Development

The National Institutes of Child Health and Human Development (NICHD) is seeking organizations to maintain and distribute four mouse models for neural tube defects to the scientific community. The organization needs to have expertise and the facilities to house and maintain breeding stocks of mutant mice and the capability to distribute them to interested investigators in a timely manner.

This announcement is a recompetition of an existing contract. The issuance of the RFP will be on August 17, 1994, and proposals will be due by 4:00 pm, EST, October 12, 1994. The NICHD expects to make one award from this solicitation.

All requests must cite the RFP number and written requests should include two self addressed mailing labels. All sources who consider themselves qualified are encouraged to submit a proposal. This does not commit the Government to making an award. Requests for the RFP are to be addressed to:

Mrs. Lynn Salo
Office of Grants and Contracts
National Institute of Child Health and Human Development
6100 Building, Room 7A07
Bethesda, MD 20892
Telephone: (301) 496-4611
FAX: (301) 402-3676

NUTRIENT MODULATION OF CELL INTEGRITY AND REPAIR MECHANISMS

NIH GUIDE, Volume 23, Number 30, August 12, 1994

RFA AVAILABLE: DK-94-023

P.T. 34; K.W. 1002004, 1002008, 0710095, 0765020

National Institute of Diabetes and Digestive and Kidney Diseases
National Cancer Institute
National Institute on Aging
National Institute on Alcohol Abuse and Alcoholism
National Institute of Allergy and Infectious Diseases
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Child Health and Human Development
National Institute on Deafness and Other Communication Disorders
National Institute of Dental Research
National Institute of Environmental Health Sciences
National Institute of Neurological Disorders and Stroke
Office of Research on Minority Health

Application Receipt Date: November 18, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

This RFA is designed to encourage research grant applications focusing on mechanisms (primarily molecular and genetic mechanisms) that underlie nutrient modulation of cellular repair processes and maintenance of cellular integrity. Research should be aimed at the normal processes involved in the effects of specific nutrients or their metabolites on cellular, genetic, and metabolic functions as well as elucidation of defective mechanisms. This initiative should offer unique opportunities afforded by the basic sciences and new technologies (e.g., molecular biology, NMR, ESR, PET) to enrich nutrition sciences.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Nutrient Modulation of Cell Integrity and Repair Mechanisms, is related to the priority areas of nutrition, physical activity and fitness, heart disease and stroke, cancer, and diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, hospitals, laboratories, units of State and local government and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) award. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Support of this program will be through the research project grant (R01) and FIRST (R29) award. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the PHS Grants Policy Statement.

This RFA is a one-time solicitation. Generally, future unsolicited competing continuation applications will compete with all investigator-initiated applications and will be reviewed by a DRG study section. The total project period for applications submitted in response to the present RFA may not exceed five years. A maximum of three years may be requested for foreign awards. The maximum dollar request for R01s is limited to \$160,000 in direct costs for the initial budget period. The earliest possible award date will be July 1, 1995.

FUNDS AVAILABLE

For FY 1995, \$4 million will be committed to fund applications submitted in response to this RFA. It is anticipated that 20 to 25 awards will be made. However, this funding level is dependent upon the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the participating Institutes, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

APPLICATION PROCEDURES

Applications are to be submitted on the research grant application form PHS 398 (rev. 9/91), available in the office of sponsored research at most academic or research institutions and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301-594-7248. The RFA label available in the PHS 398 application form must be affixed to the bottom of the face page. Detailed instructions on submission procedures are described in the RFA.

REVIEW CONSIDERATIONS

Applications that are complete and responsive to the RFA will be evaluated by an appropriate peer review group convened by the NIH in accordance with the usual peer review procedures. Following review, the applications will be given a secondary review by an Institute Advisory Council/Board unless not recommended for further consideration by the initial review group. Applications that are incomplete or unresponsive to the RFA will be returned to the applicant or held until the next regular receipt date and reviewed by the Division of Research Grants.

AWARD CRITERIA

The anticipated date of award is July 1, 1995. The following will be considered in making funding decisions.

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Programmatic balance among the studies recommended for funding

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Requests for the RFA and inquiries regarding programmatic issues may be directed to:

Michael K. May, Ph.D.
Division of Digestive Diseases and Nutrition
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A18A
Bethesda, MD 20892
Telephone: (301) 594-7520
FAX: (301) 594-7504

Inquiries regarding fiscal matters may be directed to:

Ms. Paulette Badman
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 639
Bethesda, MD 20892
Telephone: (301) 594-7543
FAX: (301) 594-7594

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.848. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ENHANCING FAMILY CAREGIVING FOR ALZHEIMER'S DISEASE AND RELATED DISORDERS

NIH GUIDE, Volume 23, Number 30, August 12, 1994

RFA AVAILABLE: AG-94-003

P.T. 34; K.W. 0715180, 0730052

National Institutes on Aging

Letter of Intent Receipt Date: October 1, 1994

Application Receipt Date: November 29, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute on Aging (NIA) invites applications for cooperative agreements for (a) sites to carry out social and behavioral research on interventions designed to enhance family caregiving for Alzheimer's disease and related disorders (ADRD) and (b) a Coordinating Center to provide coordination for this set of research projects. Theory-based interventions may consist of psycho/social/educational services (i.e., individual and/or family counseling by professionals or peers), behavioral technology (skill-training), innovations in community services (i.e., modifications in respite services, day care, home care), high-tech environmental modifications (e.g., computerized telephone systems, computer networks, etc.), or any combination of these. Given the paucity of prior controlled studies, this initiative is designed to examine the feasibility and outcomes of different intervention approaches rather than to provide definitive information on the one best intervention strategy for enhancing dementia-specific family caregiving.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Interventions for Enhancing Family Caregiving for ADRD, is related to the priority area of older adults and preventive services. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. No foreign or international components will be considered in this RFA. Applications from minorities and women are encouraged.

MECHANISM OF SUPPORT

The administrative and funding instrument to be used for this program will be a cooperative agreement (U01), an assistance mechanism (rather than an acquisition mechanism), in which substantial NIH scientific and/or programmatic involvement with the awardee is anticipated during performance of the activity. Under the cooperative agreement, the NIH purpose is to support and/or stimulate the recipient's activity by involvement in, and otherwise working jointly with, the award recipient in a partner role, but it is not to assume direction, prime responsibility, or a dominant role in the activity. Applicants will be responsible for the planning, direction, and execution of their individual proposed project and for planning and participating in collaborative activities with other award recipients under this RFA. The duration for this research endeavor is five years, with an anticipated award date of August 1, 1995.

FUNDS AVAILABLE

It is expected that up to \$2,050,000 million (total cost) for first year expenses will be available in Fiscal Year 1995 to fund five Clinical Sites plus a Coordinating Center. While separate applications must be submitted if an institution seeks selection as both a Site and Coordinating Center, any one institution may only apply for one Site and/or one Coordinating Center. The requested total funding (direct plus indirect costs) for the first-year may not exceed an average of \$350,000 for Clinical Site applications and \$300,000 for Coordinating Center applications. For the entire five years of the project, total (direct plus indirect) costs requested may not exceed \$1.9 million for each of the individual research projects, and \$1.6 million for the Coordinating Center. Although this program is provided for in the financial plans of the NIA, the award of grants pursuant to this RFA is contingent upon receipt of applications of high scientific merit and upon the availability of funds.

RESEARCH OBJECTIVES

The primary goal of this RFA is to examine the effectiveness of social and behavioral interventions to help family members care for individuals with ADRD. This RFA is not designed to support large scale demonstration programs. However, building on such studies is appropriate and encouraged if key definitions and measures are not predetermined by the initial study. The cooperative nature of this award provides a mechanism for establishing standardized outcome measures, particularly those of well-being and burden, to be used to assess the impact of different strategies on

caregivers and, secondarily, on care receivers.

Specific Research Foci

Investigators must propose at least one social and behavioral intervention. While this is not a drug trial study per se, investigators may propose a drug arm as a comparison treatment strategy. Proposed research designs must rule out alternative explanations for intervention effects. All applicants must address:

The nature of the proposed intervention (e.g., type, intensity, duration, frequency) and the underlying behavioral or social theory for expected outcomes. Previous research providing some support for the effectiveness of the proposed intervention is recommended.

Clinical, behavioral or social factors that might affect the impact of the proposed intervention. Investigators must identify and propose standardized measurements for assessing key variables, such as disease characteristics (e.g., stage of disease, presence of co-morbid conditions); caregiving characteristics (nature and extent of caregiving responsibilities; time in caregiving role); and caregiver characteristics (e.g., definition of primary caregiver; relationship of caregiver).

Intervention outcomes for caregivers and care receivers. All investigators must propose at least one primary health or functional outcome for each that would be common across all Sites. At least one common measure of caregiver burden (or its obverse, caregiver well-being) must also be identified. Other outcomes may be proposed if well justified and not burdensome for study participants). A final selection of common measures will be made by the steering committee from among those proposed.

For those who propose more than one intervention, the comparison of different interventions in terms of their health outcomes and relative costs.

Persons with medical diagnoses of ADRD, at the mild or moderate stage, are the preferred target group as are caregivers who are at increased risk due to burdens of care. All applicants should provide their working definition of a "primary caregiver"; while theoretically interesting attention to "secondary" and "tertiary" caregivers is optional. Attention should be paid to anticipated changes in the health and functioning of the person needing care for ADRD as well as in caregiver responsibilities and roles. The proposed timing and frequency of data collection for proposed outcome measures should be indicated and related to projected rates of change. Although research designs are expected to vary according to specific interventions being examined, baseline common core data should be collected and transmitted to the coordinating center, as soon as available, beginning no later than the start of the second year of the project.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the March 18, 1994 "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are encouraged to submit, by October 1, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information allows NIA staff to estimate the potential review workload and to avoid conflict of interest in the review. The letter of intent is to be sent to Dr. Marcia Ory at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted on the PHS 398 (rev. 9/91) application form. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from the NIA program administrator listed under INQUIRIES. The RFA label contained in the application kit must be affixed at the bottom of the face page of the application. Failure to use this label could delay processing of the application. In addition, the RFA title, number and type of application: "Clinical Site or "Coordinating Center," must be typed on line 2a of the face page of the application form and the YES box must be checked. Submit a signed, original of the application, including the Checklist, and three signed, exact photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Two copies of the application with appendices must also be sent to:

Chief, Scientific Review Office
National Institute on Aging
Gateway Building, Suite 2C212
Bethesda, MD 20892

The deadline for receipt of applications is November 29, 1994. Materials will not be accepted after this date.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Incomplete and nonresponsive applications will be returned to the applicant without further consideration. Those applications that are complete and responsive will be evaluated for scientific/technical merit by an appropriate peer review group convened by the NIA. Applications may be subjected to triage by a NIA peer review group to determine their scientific merit relative to other applications received in response to this RFA.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

The letter of intent and requests for the RFA may be addressed to:

Dr. Marcia Ory
Behavioral and Social Research Program
National Institute on Aging
Gateway Building, Room 533
Bethesda, MD 20892
Telephone: (301) 496-3136

Direct inquiries regarding fiscal matters to:

Ms. Joanne Colbert
Grants and Contracts Management Office
National Institute on Aging
Gateway Building, Room 2N212
Bethesda, MD 20892
Telephone: (301) 496-1472

Other institutes and agencies are also interested in research dealing with Alzheimer's disease and related disorders. For information concerning related research interests, contact:

National Institute of Nursing Research, Dr. Mary Lucas, Westwood Building, Room 754, Bethesda, MD 20892, (301) 594-7397

National Institute of Mental Health, Dr. Enid Light, Parklawn Building, Room 7103, Rockville, MD 20857, (301) 443-1185

Agency for Health Care Policy and Research: Ms. Linda Siegenthaler, 2101 E. Jefferson St, Room 502, Rockville, MD 20852, (301) 594-1357

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.866 (Aging Research). Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations, 42 CFR Part 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

5333 Westbard Avenue
Bethesda, MD 20816



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NIH GUIDE

For Grants and Contracts

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Building 31, Bethesda, Maryland 20892

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 32
August 26, 1994

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THE NIH GUIDE FOR GRANTS AND CONTRACTS WILL NOT BE PUBLISHED ON SEPTEMBER 1 AND SEPTEMBER 9. THE NEXT ISSUE OF THE NIH GUIDE WILL BE ON SEPTEMBER 16, 1994.

ATTENTION: *The new mailing list for the NIH Guide will be activated in September. Until then, the existing mailing list will be maintained. See INTENT TO MODIFY (NIH Guide, Vol. 23, No. 23, June 17, 1994) for additional information.*

This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

THE PUBLIC HEALTH SERVICE (PHS) STRONGLY ENCOURAGES ALL GRANT RECIPIENTS TO PROVIDE A SMOKE-FREE WORKPLACE AND PROMOTE THE NON-USE OF ALL TOBACCO PRODUCTS. THIS IS CONSISTENT WITH THE PHS MISSION TO PROTECT AND ADVANCE THE PHYSICAL AND MENTAL HEALTH OF THE AMERICAN PEOPLE.

SMALL BUSINESS TECHNOLOGY TRANSFER PROGRAM

NIH GUIDE, Volume 23, Number 32, August 26, 1994

AUG 31 1994

P.T. 34; K.W. 0710030

National Institutes of Health

National Institutes of Health

Application Receipt Date: December 1, 1994

Innovative technologies and methodologies fuel progress in biomedical and behavioral research and represent an increasingly important area of the economy. The Small Business Technology Transfer (STTR) program provides support to small business concerns -- in collaboration with U.S. research institutions -- for research or research and development (R&D) of new technologies and methodologies that have the potential to succeed as commercial products.

The purpose of this notice is to inform the public about the opportunities that the STTR program offers to small business concerns as well as to scientists at research institutions, including colleges and universities.

The applicant organization must be the small business concern. At least 40 percent of the project is to be performed by the small business concern and at least 30 percent is to be performed by the research institution.

The STTR program is a three-year pilot program that began in fiscal year (FY) 1994 and consists of the following three phases;

Phase I: The objective of this phase is to determine the scientific, technical, and commercial merit and feasibility of the proposed cooperative effort and the quality of performance of the small business concern, prior to providing further Federal support in Phase II.

Phase II: The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application.

Phase III: The objective of this phase, where appropriate, is to pursue with non-STTR funds the commercialization of the results of the research or R&D funded in Phases I and II.

The amount and period of support for STTR awards are as follows:

Phase I: Awards may not exceed \$100,000 for direct costs, indirect costs, and negotiated fixed fee for a period normally not to exceed one year.

Phase II: Awards may not exceed \$500,000 for direct costs, indirect costs, and negotiated fixed fee for a period normally not to exceed two years, that is, generally, a two-year Phase II project may not cost more than \$500,000 for that project. A Phase I award must have been issued in order to apply for a Phase II award. (ONLY Phase I awards will be issued in FY 1995.)

It is anticipated that approximately 80 STTR Phase I grants will be awarded by the NIH in FY 1995 from funds set aside for this purpose.

INQUIRIES

Eligibility requirements, definitions, application procedures, review considerations, application forms and instructions, and other pertinent information are contained in the OMNIBUS SOLICITATION OF THE NATIONAL INSTITUTES OF HEALTH FOR SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) GRANT APPLICATIONS. The Solicitation, which is for the single application receipt date of December 1, 1994, for grant awards to be made in FY 1995, will be available the middle of September 1994.

Hard copies of the NIH STTR Solicitation are available directly from the following office ONLY:

PHS SBIR/STTR Solicitation Office
13687 Baltimore Avenue
Laurel, MD 20707-5096
Telephone: (301) 206-9385
FAX: (301) 206-9722
Internet: a2y@cu.nih.gov

In addition, the Solicitation will be available electronically using Business Gold, the National Technology Transfer Center's bulletin board system. (This does NOT include STTR application forms, which should be obtained in hard copy from the PHS SBIR/STTR Solicitation Office above.) Connect via Internet by telnetting to "iron.nttc.edu" or by dialing (304) 243-2560 for high speed modems (9600+) or (304) 243-2561 for 1200-2400 baud modems and logging in as "guest." For more information on their electronic bulletin board system, contact:

National Technology Transfer Center
Wheeling Jesuit College
316 Washington Avenue
Wheeling, WV 26003-6295
Telephone: (800) 678-6882 (toll-free within U.S.)

Following are contact points for discussion of program interests pertaining to the NIH awarding components participating in the STTR grant program:

Dr. Miriam F. Kelty
Office of Extramural Affairs
National Institute on Aging
7201 Wisconsin Avenue, Suite 2C218
Bethesda, MD 20892
Telephone: (301) 496-9322
FAX: (301) 402-2945
Internet: mk46u@nih.gov

Dr. Laurie Foudin
National Institute on Alcohol Abuse and Alcoholism
6000 Executive Boulevard, Suite 402
6000 EXECUTIVE BLVD MSC 7003
Bethesda, MD 20892-7003
Telephone: (301) 443-4224
FAX: (301) 594-0673
Internet: lf29z@nih.gov

Mr. Allan Czarra
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3C28
Bethesda, MD 20892
Telephone: (301) 496-7291
FAX: (301) 402-0369
Internet: ac20a@nih.gov

Dr. Michael Lockshin
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Building 31, Room 4C32
Bethesda, MD 20892
Telephone: (301) 496-0802
FAX: (301) 480-6069
Internet: ml47h@nih.gov

Ms. Jo Anne Goodnight
Cancer Biology and Diagnosis
National Cancer Institute
Executive Plaza North, Room 500
Bethesda, MD 20892
Telephone: (301) 496-5307
FAX: (301) 496-8656
Internet: jg128w@nih.gov

Dr. Jack Gruber
Cancer Etiology
National Cancer Institute
Executive Plaza North, Room 540
Bethesda, MD 20892
Telephone: (301) 496-9740
FAX: (301) 496-2025
Internet: jg65y@nih.gov

Dr. Ruthann M. Giusti
Cancer Treatment
National Cancer Institute
Building 31, Room 3A49
Bethesda, MD 20892
Telephone: (301) 496-6404
FAX: (301) 496-0826
Internet: rg39r@nih.gov

Dr. Barry Portnoy
Cancer Prevention and Control
National Cancer Institute
Building 31, Room 10A49
Bethesda, MD 20892
Telephone: (301) 496-1071
FAX: (301) 496-9931
Internet: bp22z@nih.gov

Ms. Connie Dresser
Interactive Multimedia Technologies for Cancer Prevention
National Cancer Institute
Executive Plaza North, Room 241
Bethesda, MD 20892
Telephone: (301) 496-0273
FAX: (301) 496-8675
Internet: cd34b@nih.gov

Ms. Hildegard Topper
National Institute of Child Health and Human Development
Building 31, Room 2A03
Bethesda, MD 20892
Telephone: (301) 496-0104
FAX: (301) 402-1104
Internet: ht20t@nih.gov

Ms. Jacqueline P. Downing
National Institute on Drug Abuse
Parklawn Building, Room 10A-55
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-1056
FAX: (301) 443-6277
Internet: jd96j@nih.gov

Dr. Daniel A. Sklare
Division of Communication Sciences and Disorders
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Room 400-C
6120 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-1804
FAX: (301) 402-6251
Internet: ds104i@nih.gov

Dr. Joyce A. Reese
National Institute of Dental Research
Westwood Building, Room 509
Bethesda, MD 20892
Telephone: (301) 594-7648
FAX: (301) 594-9720
Internet: r2j@cu.nih.gov

Mr. John R. Garthune
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 637
Bethesda, MD 20892
Telephone: (301) 594-7569
FAX: (301) 594-7594
Internet: jg60d@nih.gov

Dr. Michael J. Galvin, Jr.
Environmental Health Resources Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
104 Alexander Drive, MD 3-03
Research Triangle Park, NC 27709
Telephone: (919) 541-7825
FAX: (919) 541-2843
Internet: mg63c@nih.gov

Dr. Ralph Helmsen
National Eye Institute
Executive Plaza South, Suite 350
6120 EXECUTIVE BLVD MSC 7164
Bethesda, MD 20892-7164
Phone: (301) 496-5301
FAX: (301) 402-0528
Internet: rh27v@nih.gov

Dr. Michael R. Martin
National Institute of General Medical Sciences
Westwood Building, Room 936
Bethesda, MD 20892
Telephone: (301) 594-7753
FAX: (301) 594-7731
Internet: mm72k@nih.gov

Dr. David Robinson
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 416
Bethesda, MD 20892
Telephone: (301) 496-5656
FAX: (301) 402-3508
Internet: dr14j@nih.gov

Dr. Thomas Blaszkowski
Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
Federal Building, Room 208A
Bethesda, MD 20892
Telephone: (301) 496-1841
FAX: (301) 496-0075
Internet: tb33i@nih.gov

Dr. Carol Vreim
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 6A16
Bethesda, MD 20892
Telephone: (301) 594-7430
FAX: (301) 594-7408
Internet: cv2@cu.nih.gov

Dr. George Nemo
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building, Room 504
Bethesda, MD 20892
Telephone: (301) 496-1537
FAX: (301) 496-4843
Internet: gn6y@nih.gov

Dr. Michael Huerta
National Institute of Mental Health
Parklawn Building, Room 11-103
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4885
FAX: (301) 443-4822
Internet: hmi@cu.nih.gov

Mr. Edward Donohue
National Institute of Neurological Disorders and Stroke
Federal Building, Room 1016
Bethesda, MD 20892
Telephone: (301) 496-4188
FAX: (301) 402-4370
Internet: ed25b@nih.gov

Dr. Judith Laughlin
National Institute of Nursing Research
Westwood Building, Room 738
Bethesda, MD 20892
Telephone: (301) 594-7493
FAX: (301) 594-7603
Internet: jl97v@nih.gov

Dr. Louise E. Ramm
National Center for Research Resources
Westwood Building, Room 854
Bethesda, MD 20892
Telephone: (301) 594-7906
FAX: (301) 594-9121
Internet: lr34m@nih.gov

Dr. Bettie J. Graham
National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531
FAX: (301) 480-2770
Internet: bg30t@nih.gov

Mr. Peter Clepper
National Library of Medicine
Building 38A, Room 5S518
Bethesda, MD 20894
Telephone: (301) 496-4221
FAX: (301) 402-0421
Internet: pc49n@nih.gov

P.T. 34; K.W. 0710030

National Institutes of Health
Centers for Disease Control and Prevention

Contract Proposal Receipt Date: December 5, 1994

The purpose of this notice is to (1) announce the issuance of the SOLICITATION OF THE PUBLIC HEALTH SERVICE FOR SMALL BUSINESS INNOVATION RESEARCH (SBIR) CONTRACT PROPOSALS with a due date for receipt of proposals of December 5, 1994; and (2) inform the public about the opportunities that the SBIR program offers to small business concerns as well as to scientists at research institutions, including colleges and universities. Public Law 102-564, signed by the President October 28, 1992, requires the Public Health Service (PHS), Department of Health and Human Services, and certain other Federal agencies to reserve a specified amount of their extramural research or R&D budgets for an SBIR program. In fiscal years 1995 and 1996, 2.0 percent of the PHS extramural budget will be reserved for the SBIR program, amounting to \$170-\$175 million (estimated); and in fiscal years 1997 and beyond, the set-aside requirement will be 2.5 percent.

The offeror organization must be a small business concern, and the primary employment of the principal investigator MUST be with the small business concern at the time of award and during the conduct of the proposed project. In accord with the intent of the SBIR program to increase private sector commercialization of innovations derived from Federal R&D, scientists at research institutions can play an important role in an SBIR project by serving as consultants and/or subcontractors to the small business concern. Normally, up to one-third of the Phase I budget may be spent on consultant and/or subcontractual costs, and up to one-half of the Phase II budget may be spent on such costs. In this manner, a small business concern with limited expertise and/or research facilities may benefit from teaming with a scientist at a research institution; for the scientist at a research institution, this team effort provides support for R&D not otherwise obtained.

The SBIR program consists of the following three phases:

PHASE I: The objective of this phase is to determine the scientific and technical merit and feasibility and potential for commercialization of the proposed research or R&D efforts and the quality of performance of the small business concern, before consideration of further Federal support in Phase II.

PHASE II: The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II proposal. Only Phase I contractors are eligible to apply for Phase II funding, and Phase II proposals may be submitted upon the request of the Contracting Officer ONLY.

PHASE III: The objective of this phase, where appropriate, is for the small business concern to pursue with non-SBIR funds the commercialization of the results of the research or R&D funded in Phases I and II.

The amount and period of support for SBIR awards are as follows:

PHASE I: Awards may not exceed \$100,000 for direct costs, indirect costs, and negotiated fixed fee for a period normally not to exceed six months.

PHASE II: Awards may not exceed \$750,000 for direct costs, indirect costs, and negotiated fixed fee for a period normally not to exceed two years, that is, generally, a two-year Phase II project may not cost more than \$750,000 for that project. Only one Phase II award may be made for any SBIR project.

INQUIRIES

Eligibility requirements, definitions, submission procedures, review considerations, contract proposal forms and instructions, and other pertinent information are contained in the Solicitation of the PHS for SBIR Contract Proposals, available the middle of September from:

PHS SBIR/STTR Solicitation Office
13687 Baltimore Avenue
Laurel, MD 20707-5096
Telephone: (301) 206-9385
FAX: (301) 206-9722
Internet: a2y@cu.nih.gov

In addition, the ENTIRE Solicitation will be available electronically using Business Gold, the National Technology Transfer Center's bulletin board system. Connect via Internet by telneting to "iron.nttc.edu" or by dialing (304) 243-2560 for high speed modems (9600+) or (304) 243-2561 for 1200-2400 baud modems and logging in as "guest". For more information on their electronic bulletin board system, contact:

National Technology Transfer Center
Wheeling Jesuit College
316 Washington Avenue
Wheeling, WV 26003-6295
Telephone: (800) 678-6882 (toll-free within U.S.)

Anyone interested in the PHS SBIR Grant program may obtain the current edition of the OMNIBUS SOLICITATION OF THE PHS FOR SBIR GRANT AND COOPERATIVE AGREEMENT APPLICATIONS from the above sources also. See also the NIH GUIDE FOR CONTRACTS AND GRANTS, Volume 23, Number 15, April 15, 1994.

NIH GUIDE, Volume 23, Number 32, August 26, 1994

P.T. 34, FF; K.W. 0710030

National Institute on Drug Abuse

PURPOSE

The purpose of this notice is to inform the research community that the National Institute on Drug Abuse (NIDA) will accept competing continuation (renewal) applications for participation in the Minority Institutions Research Development Program (MIRDP). The MIRDP was designed to increase the capacity of predominantly minority institutions and their faculty to conduct alcohol, drug abuse, and mental health research. NIDA is accepting renewal applications specific to drug abuse research.

APPLICATION PROCEDURES

Renewal applications are to be submitted on the grant application form PHS 398 (rev. 9/91), with a cover letter indicating the request for renewal. The application face page must also indicate across top margin "RENEWAL APPLICATION" and must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Renewals must be received in accordance with the standard receipt dates for competing continuation (renewal) applications (i.e., March 1, July 1, and November 1).

Competing continuation (renewal) applications must include a progress report containing the following information:

1. Summary of institution's research projects developed or expanded through the MIRDP award;
2. Outline of drug abuse-related research development activities by institution, faculty and staff;
3. Demonstration of increased involvement or interest by minority students in drug-related research projects or pursuing drug-related research careers through participation in MIRDP-sponsored activities;
4. Review of any infrastructure enhancements to institution, including faculty ability to conduct drug abuse-related research. Include any examples of laboratory improvement, faculty development, data and statistical analysis capability, resource development, and the like.

The competing continuation (renewal) application should, as in the original: (1) assess the current institutional and faculty capacity to conduct drug-related research, (2) identify unmet needs, and (3) describe the activities to further develop the institutional infrastructure and faculty capacity to conduct drug research. The continuation application should include both an institutional research development program and one or more individual investigator projects.

The applicant must submit a budget detailing the costs associated with the proposed renewal, including personnel (percent effort, rate, and fringe benefits), supplies and equipment, shipping and handling expenses, laboratory costs, and expenses for study subjects including travel reimbursements, if applicable.

The NIH peer review process will be used. A NIDA study section with expertise in the subject area will evaluate the scientific merit of the application, using evaluation criteria described in the MIRDP program announcement dated April 1989.

INQUIRIES

Questions regarding programmatic aspects and matters pertaining to the review of the application may be directed to:

Lula A. Beatty, Ph.D.
Special Populations Office
National Institute on Drug Abuse
5600 Fishers Lane
Parklawn Building, Room 10A08
Rockville, MD 20857
Telephone: (301) 443-0441

Questions regarding administrative or budgetary issues may be directed to:

Gary Fleming
Grants Management Branch
National Institute on Drug Abuse
5600 Fishers Lane
Parklawn Building, Room 8A54
Rockville, MD 20857
Telephone: (301) 443-6710

AVAILABILITY OF FISH OIL TEST MATERIALS

NIH GUIDE, Volume 23, Number 32, August 26, 1994

P.T. 34; K.W. 0780017

National Institutes of Health

This notice supplements the previous announcement published in the NIH Guide for Grants and Contracts, Vol. 19, No. 11, March 16, 1990.

SUMMARY AND PURPOSE

Additional Test Materials Currently Available

The Fish Oil Test Materials Program announces the availability of purified EPA (approx. 90 %) and DHA (approx. 90%) in kilogram quantities to qualified applicants conducting research studies.

- o EPA ethyl ester, packaged in 1 gm soft gelatin capsules (contain tocopherols(1-2 mg/g) and TBHQ(.02%)
- o DHA ethyl ester, packaged in 1 gm soft gelatin capsules (contain tocopherols(1-2 mg/g) and TBHQ(.02%)
- o Placebo ethyl esters, packaged in 1 gm soft gelatin capsules (described with other products listing)

Processing and Specifications of Biomedical Test Materials

o EPA Ethyl Ester

The ethyl ester of EPA is prepared from fish oil using transesterification, short-path distillation and urea adduction to yield an n-3 ethyl ester concentrate. The purified ethyl ester of EPA is attained by preparative chromatographic techniques. The product contains 95% ethyl esters; of the ethyl esters EPA is 95%, other n-3's are <4%, n-6's are <1% and other fatty acid esters are <1%. It contains 0.2 mg/g TBHQ as antioxidant and 2 mg/g tocopherols.

o DHA Ethyl Ester

The ethyl ester of DHA is prepared from fish oil using transesterification, short-path distillation and urea adduction to yield an n-3 ethyl ester concentrate. The purified ethyl ester of DHA is attained by preparative chromatographic techniques. The product contains >95% ethyl esters; of the ethyl esters DHA is 86%, other n-3's are <9%, n-6's are <3% and other fatty acid esters are <1%. It contains 0.2 mg/g TBHQ as antioxidant and 2 mg/g tocopherols.

FISH OIL TEST MATERIALS PROGRAM

The Fish Oil Test Materials Program is administered by the National Institute on Alcohol Abuse and Alcoholism, NIH. The program was established in 1986 through the cooperation of the National Institutes of Health (NIH), the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), and the National Oceanic and Atmospheric Administration/Department of Commerce (NOAA/DOC). This program has been designed to provide a long-term, consistent supply of quality-assured/quality-controlled test materials to researchers to facilitate the evaluation of the role of omega-3 fatty acids in health and disease.

Fish Oil Test Materials Advisory Committee

A Fish Oil Test Materials Advisory Committee (FOTMAC) is chaired by scientific staff from NIH and is composed of scientists representing the funding agencies (NIH), the research community, Department of Commerce (DOC) and the Food and Drug Administration (FDA). The FOTMAC provides scientific advice to the DOC regarding the types of materials needed by research scientists, shipping procedures for the materials, and additional quality control and production issues. The committee is advisory to the Fish Oil Test Materials Program on general programmatic issues such as future directions, and has produced an information sheet on Considerations in the Study of the Effects of Dietary Fish Oils. In addition, the committee provided guidance to DOC during the production of the Drug Master File submitted to the FDA by the FOTMAC. Manuals on Analytical Methods for the Quality Assurance of Fish Oil, Production Methods/Safety and Distribution were produced by the DOC and are available to investigators.

Fish Oil Test Materials Distribution Committee

A Fish Oil Test Materials Distribution Committee (FOTMDC) is composed of NIH and other Federal scientists. The Distribution committee processes the applications received from investigators, advises the DOC of applicants that have fulfilled the application process, and makes recommendations regarding the distribution of requested materials.

Other Test Materials Currently Available

- o n-3 ethyl ester concentrate, prepared from menhaden oil, bulk packed or soft-gel encapsulated (80% n-3 fatty acids including EPA and DHA)
- o Ethyl esters of olive oil, corn oil, and safflower oil (70% linoleic), bulk packed or soft-gel encapsulated
- o Deodorized menhaden oil, bulk packed or soft-gel encapsulated
- o Commercial preparations of corn, olive, or safflower oil, soft-gel encapsulated only
- o DHA Ethyl Ester and EPA Ethyl Ester in small gram quantities, bulk packed

o n-3 Ethyl Ester Concentrate

The n-3 ethyl ester concentrate is prepared from vacuum-deodorized menhaden oil using transesterification, urea adduction and short-path distillation. The concentrate contains >90% ethyl esters, of which approximately 80% are n-3 fatty acid ethyl esters (44% EPA, 24% DHA, 10-12% other n-3 fatty acid ethyl esters), 3% C18 (other than n-3), 6% C16 and the remainder as other esters. It contains 0.2 mg/g TBHQ as antioxidant, 2 mg/g tocopherols and 2.0 mg/g cholesterol. The concentrate is available in 1 g soft-gel capsules (100 capsules/bottle) or packaged in bulk in quantities suitable to investigators' needs.

o Placebo Ethyl Esters

The olive, corn and safflower ethyl esters contain >85% esters. The olive oil ethyl esters contain approximately 70% oleic acid, 10% C16, and 6% C18 (<6 mg/g n-3) fatty acid ethyl esters. The corn oil ethyl ester contains approximately 50% linoleic, 23% oleic acid and 10% C16 (>6 mg/g n-3) fatty acids. The safflower ethyl esters contain approximately 72% linoleic, 8% oleic and 6% C16 (>2 mg/g n-3) fatty acids. The preparations are available in 1 g soft-gel capsules (100 capsules/bottle) or packaged in bulk in quantities suitable to investigators' needs.

o Deodorized Menhaden Oil

Deodorized menhaden oil is prepared from oil that has been winterized and alkali refined; it is processed through a two stage wiped-film evaporator to remove cholesterol, volatile oxidation products and any traces of organic contaminants. The oil contains approximately 30% n-3 fatty acids in the triglyceride form; 14% EPA, 8% DHA, 8% other n-3. It contains 0.2 mg/g TBHQ as antioxidant, 2 mg/g tocopherols and 2.0 mg/g cholesterol. The deodorized oil is available in 1 g soft-gel capsules (100 capsules/bottle) or is packaged in bulk quantities suitable to investigators' needs. Special requests for antioxidants-free oil will be considered, e.g., for studies involving varying levels of antioxidants.

o Placebo Oils

Commercial preparations of corn, olive, and safflower oil have been soft-gel encapsulated to serve as placebos for studies involving encapsulated menhaden oil. These oils contain 0.2 mg/g TBHQ as antioxidant and 2 mg/g tocopherols. The major fatty acids for each oil are: corn (58% 18:2n-6, 26% 19:1n-9) olive 17% 18:2n-6, 57% 18:1n-9), safflower 80% 18:2n-6, 9% 18:1n-9). They are available in 1 g soft-gel capsules (100 capsules/bottle). Although vegetable oils will not be supplied in bulk form, investigators may request analysis of antioxidants and tocopherol levels in vegetable oils that they purchase for their studies.

APPLICATION PROCEDURES

To qualify to receive materials described in this announcement the applicant must: (1) have peer-reviewed research indicating the need for the requested materials, and (2) submit a correctly completed application form and a signed waiver of liability. The committee will not be responsible for assessing the scientific merit of the application. Regulations on human subjects and animal research apply. In accordance with federal regulations, an IND number will be required for the use of these materials in human studies. The FOTMAC has established a drug master file at the FDA that includes manufacturing, chemical composition, and toxicological data relevant to these products. Investigators approved for the use of NOAA/DOC materials may reference this file in order to expedite their IND requests. Availability of materials are contingent on DOC/NOAA production capabilities. When prioritization is necessary, the order will be: (1) NIH funded, (2) other U.S. government funded, (3) peer-reviewed, other funded, (4) NIH approved, not funded, and (5) other.

Kilogram quantities of purified EPA ethyl ester and DHA ethyl ester are available for research purposes. The awarded materials are provided free of charge (Researchers are asked to pay shipping costs). For further information, contact Dr. Patricia Fair at (803) 762-1200.

Additional information will be provided to the investigator including extensive quality assurance data for each lot of test material shipped, stability data and storage instructions.

INQUIRIES

Investigators may obtain further information and apply for available fish oil test materials for relevant studies by requesting an application form from:

Fish Oil Test Materials Program
Program Coordinator
National Institute on Alcohol Abuse and Alcoholism
DANAC #4, Room 55C
12501 Washington Avenue
Rockville, MD 20852
Telephone: (301) 443-2393
FAX: (301) 594-0035

CARDIOVASCULAR HEALTH STUDY-MAGNETIC RESONANCE IMAGES READING CENTER

NIH GUIDE, Volume 23, Number 32, August 26, 1994

RFP AVAILABLE: NHLBI-HC-94-32

P.T. 34; K.W. 0706030, 0785055

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) requires a reading center to continue work begun in 1991 for interpretation of cerebral magnetic resonance images (MRI) performed in the epidemiological research study of the major factors contributing to the occurrence of heart disease and stroke in elderly adults entitled "Cardiovascular Health Study (CHS)." The MRI Reading Center will assist in protocol development for the performance of repeat cerebral MRI scans on about 3,400 participants at four CHS Field Centers, and will perform measurements and interpretations of these images in a standardized and reproducible manner. The period of performance is July 1, 1995 through May 31, 2000.

This is an announcement for a Request for Proposal (RFP). RFP NHLBI-HC-94-32 is now available. Proposals are due October 27, 1994. One award is anticipated to be made during June 1995. Interested organizations may request either a streamlined or full RFP package. If no selection is made, a streamlined version of the RFP will be provided, which includes only the Statement of Work, deliverables, reporting requirements, and technical evaluation criteria. After examination of these documents, any organization interested in responding to this RFP must request the entire RFP in writing or by FAX.

Telephone requests will only be honored if confirmed by FAX or written request. All requests for RFP must cite RFP No. NHLBI-HC-94-32.

INQUIRIES

Requests for copies of the RFP may be directed to:

Patricia A. Smith
Division of Extramural Activities
National Heart, Lung, and Blood Institute
Federal Building, Room 3C16
Bethesda, MD 20892
FAX: (301) 496-0075

NATHAN SHOCK CENTERS OF EXCELLENCE IN BASIC BIOLOGY OF AGING

NIH GUIDE, Volume 23, Number 32, August 26, 1994

RFA AVAILABLE: AG-94-006

P.T. 04; K.W. 0715210, 0710010

National Institute on Aging

Letter of Intent Receipt Date: October 15, 1994

Application Receipt Date: November 29, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute on Aging (NIA) invites applications for support of centers of excellence in research on basic biological mechanisms of aging, to be known as Nathan Shock Centers of Excellence in Basic Biology of Aging. The purpose of this core center grant is to enhance the quality of research in the basic biology of aging, facilitate the planning and coordination of aging research activities, and provide a suitable environment for fellows and junior faculty to acquire research skills and experience through support of core activities at institutions that have demonstrated commitment to, and expertise in, basic biology of aging research.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Nathan Shock Centers of Excellence in Basic Biology of Aging, is related to the priority area of chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic non-profit organizations and institutions, State and local governments and their agencies, and authorized Federal institutions. To be eligible for award as a Nathan Shock Center of Excellence, the center must currently support a minimum of fifteen peer-reviewed, externally funded research projects. In the case of currently funded program projects (P01s) or similar grants, each research component will be deemed to be a separate project. Supportive core components do not qualify. Minority individuals and women from qualifying institutions are encouraged to apply.

MECHANISM OF SUPPORT

The Nathan Shock Centers will be supported through the NIH core center grants (P30). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to this RFA may not exceed five years. The anticipated award date is July 1995.

FUNDS AVAILABLE

Support may be requested for a period of five years. The direct costs requested for the first year may not exceed \$325,000, exclusive of indirect consortium costs. Applications with budget requests exceeding this amount will not be accepted by the NIA and will be returned to the applicant. Budget increments for subsequent years will be limited to no more than four percent. Plans are to make two or three awards in fiscal year 1995 and further awards in fiscal years 1996 and 1997 depending upon availability of funds.

RESEARCH OBJECTIVES

The Core Center is a mechanism designed to enhance and extend the effectiveness of a group of related projects and investigators already funded through other mechanisms such as research project grants (R01), program projects (P01), FIRST awards (R29), MERIT awards (R37), or other Federal or non-Federal externally peer reviewed grants. In this respect, the Core Center mechanism builds upon an established base of research excellence, which emphasizes common themes or foci. Each Core Center Grant must include a core resources component and a limited program enrichment component that supports administrative functions and advisory committee expenses. Activities such as animal facilities, biometric support, molecular/cell biology and/or equipment, which must be utilized by three or more projects on aging research that are already funded, would be supported in the resources core. Core center grants also may include a research development core and an expanded program enrichment core. The expanded program enrichment core would support conferences, symposia, travel to scientific meetings and special consultants. The research development core would provide support for pilot/feasibility projects or temporary salary support to investigators just entering the research on aging arena to a point where they can compete for independent support. Such salary support usually would not exceed two years. An appropriately qualified scientist must be named as a director of each core proposed as well as a Center Director for overall direction.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

APPLICATION PROCEDURES

The applicant must submit the application using PHS 398 (rev. 9/91). Application kits containing this form and the necessary instructions are available in most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248. Applicants are urged to obtain from the NIA Scientific Review Office guidelines for preparing multicomponent applications, which contain information not found in the standard PHS 398 kit. NIA program staff are available to provide guidance on programmatic and administrative issues, in the development of the application.

REVIEW CONSIDERATIONS

Applications must be received by November 29, 1994. Upon receipt, applications will be reviewed for completeness by the Division of Research Grants (DRG), and responsiveness by NIA staff. Incomplete applications will be returned to the applicant without further consideration. If NIA staff find that the application is not responsive to the RFA, or if the first year budget request exceeds \$325,000 in direct costs, exclusive of indirect costs requested for consortiums, it will be returned without further consideration. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIA in accordance with the review criteria stated below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA. Applications judged to be competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the principal investigator/program director and the official signing for the applicant organization will be promptly notified. Because a site visit is not anticipated, each application must be thorough and complete enough to stand on its own merits. The second-level review will be made by the National Advisory Council on Aging at its May 1995 meeting, for funding beginning in July 1995. The primary criterion for review by the NIA review committee in evaluating each grant application will be the potential of the proposed center to contribute to enriching programs leading to understanding basic mechanisms of aging. It is recognized that not all criteria will be applicable to every application, depending on number and extent of proposed cores. Specific criteria are listed in the RFA.

AWARD CRITERIA

The anticipated date of the first year award will be July 1995. Funding criteria will be scientific merit (based on the review criteria listed above), availability of funds, and programmatic priorities.

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Richard L. Sprott, Ph.D.
Biology of Aging Program
National Institute on Aging
Gateway Building, Room 2C231
7201 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-4996
FAX: (301) 402-0010

Direct inquiries regarding fiscal issues to:

Robert Pike
Grants and Contracts Management Office
National Institute on Aging
Gateway Building, Room 2N212
7201 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-1472
FAX: (301) 402-3672

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.866. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ADULT AIDS CLINICAL TRIALS GROUPS

NIH GUIDE, Volume 23, Number 32, August 26, 1994

RFA AVAILABLE: AI-94-028

P.T.34; K.W. 0715008, 0755015

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: September 15, 1994
Preapplication Meeting: September 28, 1994
Application Receipt Date: January 12, 1995

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. COPIES OF THE RFA MAY BE OBTAINED FROM THE CONTACT NAMED IN "INQUIRIES", BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Allergy and Infectious Diseases (NIAID) announces the availability of an RFA to establish one or more AIDS Clinical Trials Groups (ACTG). The RFA invites applications from institutions interested in participating in a cooperative group that will perform Phase I, II, and III clinical evaluations of promising new interventions for the treatment of HIV disease, AIDS, and opportunistic diseases resulting from HIV infection, including malignancies and neurologic complications. The ACTG will conduct clinical trials involving adult participants and will be required to perform laboratory studies in virology, immunology, and pharmacology in support of the research agenda.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Adult ACTG, is related to the priority area of HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications are limited to domestic non-profit and for-profit organizations, public and private organizations, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign organizations are not eligible to apply. Applications from minority individuals and women are encouraged.

A key feature of this RFA for the Adult ACTG(s) is that it requires a Central Group application, comprised of the following components:

- o a comprehensive research agenda delineating the research goals and plan for the entire ACTG, and identifying the resources and scientific and managerial leadership needed to accomplish the agenda;
- o a plan and budget for establishing and running central Advanced Technology Laboratories in support of the research agenda specializing in virology, immunology and pharmacology;
- o an organizational and governance structure; and
- o an operations office.

The Central Group application must also identify a single Statistical and Data Management Center that will work with the group.

The Central Group application must be submitted by a single Group Leader who will serve as the Principal Investigator of the Central Group award. The identified Statistical and Data Management Center must submit a separate application, and if successful will be awarded a separate cooperative agreement.

Individual institutions, AIDS Clinical Trials Units (ACTUs) wishing to participate in a collaborative group must submit a separate application identifying the Central Group to which they are seeking membership. This application must demonstrate the applicant's ability to contribute to the research goals of the ACTG as identified in the Central Group application, and the institution's research experience and capabilities.

MECHANISM OF SUPPORT

Awards funded under this RFA will be made as Cooperative Agreements (U01). Separate cooperative agreements will be awarded to the Central Group, Statistical and Data Management Center, and to the ACTUs.

FUNDS AVAILABLE

Approximately \$60,000,000 (total cost) will be available in the first year for these awards to form one or two Adult ACTGs. Of the total cost, \$3.5 million will be reserved by the NIAID to exclusively support awards to minority institutions. The level of support will be dependent on the number of applications of high merit received, and the availability of funds. Funding beyond the initial budget period at the level awarded in the first year of support will be contingent on the continued availability of funds for this purpose, and on satisfactory progress in the preceding year.

RESEARCH OBJECTIVES

The primary goal of this initiative is to evaluate innovative therapeutic strategies and interventions for HIV infection and its complications, based upon emerging knowledge of the biology and potential therapeutic targets of HIV and associated pathogens, the pathogenesis of HIV infection and resulting opportunistic diseases, and factors influencing disease progression and treatment outcome. Further, this initiative is designed to strengthen the coordination of ACTG research with progress in basic research. This will allow the ACTG to capitalize on the latest insights into the biology of HIV and its associated pathogens and into host-pathogen relationships for the purpose of developing more effective treatments while enhancing knowledge of the pathogenesis of HIV disease and its complications.

The ACTG will play a critical role in helping to fulfill the goals and priorities of therapeutics research as outlined in the NIAID HIV/AIDS Research Agenda. (See INQUIRIES to obtain a copy of the therapeutics section of the NIAID HIV/AIDS Research Agenda.) Specifically, applications should address the following areas of research: Primary Disease Therapeutics; Immune Based Therapeutics/Immune Reconstitution; Treatment and Prevention of HIV-Related Opportunistic Infections; Oncology Treatment Research; Neurology Treatment Research; Women's Health Treatment Research; Pharmacology; and Methodology for Trials.

Special Instructions for the Preparation of Cooperative Agreement Applications

The Central Group/Operations Office application must contain: (1) a comprehensive scientific agenda and research plan, including the key resources and scientific and managerial leadership required to accomplish the stated research goals; (2) a plan and budget for establishing Advanced Technology Laboratories; (3) the organizational and managerial structure of the ACTG; (4) bylaws or a plan for establishing group bylaws including membership criteria, standards of performance, and evaluation criteria; (5) procedures for developing and executing clinical protocols and ensuring regulatory compliance; and (6) plans for the inclusion of under-represented populations in the clinical trials and the involvement of community representatives in ACTG activities.

The Statistical and Data Management Center Application must contain: (1) the organizational and managerial structure; (2) procedures for communicating with collaborating institutions; (3) design and management of the database; (4) procedures for the design, execution and analysis of clinical protocols; and (5) procedures for providing NIAID with regulatory reports and interim analyses required by the Data Safety and Monitoring Board.

ACTUs must include the following information in their applications: (1) evidence of experience in participating in multi-center HIV clinical trials; (2) proposed contributions to the scientific agenda of the Central Group to which they are applying for membership; (3) evidence of the adequate access to HIV-infected patient populations that supports accrual of, at a minimum, 75 new patients annually who are representative of the demographic characteristics of HIV/AIDS in their catchment area.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11. (To obtain copies, see INQUIRES, below).

LETTER OF INTENT

Prospective applicants are asked to submit, by September 15, 1994, a letter of intent that includes a descriptive title of the proposed application (Adult ACTG Central Group, Adult ACTU, or Adult ACTG Statistical and Data Management Center); the name, address, and telephone number of the Principal Investigator; the number and title of this RFA; a list of the key investigators and their institution(s); and for Adult ACTU and Statistical and Data Management Center applicants, the identity of the ACTG Central Group with which the applicant plans to affiliate.

The letter of intent is requested to provide an indication of the scope and number of applications that will be received and to promote early interaction among potential applicants and between the applicants and NIAID staff. Letters of intent from potential applicants for ACTG Central Group awards will be used by DAIDS program staff to refer unaffiliated potential applicants for ACTUs to potential ACTG Central Groups. The letter of intent does not commit the sender to submit an application, nor is it a requirement for submission of an application. The letter of intent is to be sent to Dr. Peter Jackson at the address listed under INQUIRES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used to apply, and is available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

The RFA label in the form PHS 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. The RFA number and title must be typed on line 2a of the face page of each component application and the "YES" box must be marked.

REVIEW CONSIDERATIONS

Applications will be reviewed by the Division of Research Grants (DRG) for completeness and by the NIAID to determine responsiveness to the RFA. Incomplete or non-responsive applications will be returned to the applicant without further consideration or review. Responsive applications will be further reviewed for scientific and technical merit by an appropriate review committee. A second level of review will be provided by the National Advisory Allergy and Infectious Diseases Council.

AWARD CRITERIA

Funding decisions will be made on the basis of scientific merit and technical proficiency as determined by peer review, program priorities, and the availability of funds for this purpose.

INQUIRES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Requests for the RFA and the "NIH GUIDELINES FOR THE INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH" as well as inquiries regarding programmatic issues may be directed to:

Frederick H. Batzold, Ph.D.
Division of AIDS
National Institute of Allergy and Infectious Diseases
Solar Building, Room 2A03
6003 Executive Boulevard MSC 7620
Bethesda, MD 20892-7620
Telephone: (301) 496-8214
FAX: (301) 480-5703

Inquiries pertaining to the review and the letter of intent may be directed to:

Peter Jackson, Ph.D.
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C14
6003 Executive Boulevard MSC 7610
Bethesda, MD 20892-7610
Telephone: (301) 496-8426
FAX: (301) 402-2638

Direct inquiries regarding fiscal issues to:

Kathryn Phillips
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B33
6003 Executive Boulevard MSC 7610
Bethesda, MD 20892-7610
Telephone: (301) 496-7075
FAX: (301) 480-3780



Schedule

Letter of Intent Receipt Date: September 15, 1994
Preapplication Meeting: September 28, 1994
Application Receipt Date: January 12, 1995
Special Review Committee: May 1, 1995
NIAID Advisory Council: September 28, 1995
Anticipated Award Date: January 1, 1996

AUTHORITIES AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, 93.856 - Microbiology and Infectious Diseases Research and 93.855 - Allergy, Immunology and Transplantation Research. Award will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended: 42 USC 241) and administered under the PHS grants policies and Federal Regulations 42 Part 74. This program is not subject to the intergovernmental review requirements of the Executive Order 12372 or Health Systems Agency review.

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

RICHARD W MURRY

* 340189
S1350E

929 WILD FOREST DRIVE
GAITHERSBURG MD 20879 3209

Vol. 23, No. 33
September 16, 1994

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NOTICES

IMPLEMENTATION OF MODIFICATIONS OF THE NIH GUIDE

NIH GUIDE, Volume 23, Number 33, September 16, 1994

P.T. 16; K.W. 1004017, 1014002

National Institutes of Health

The next issue of the NIH Guide (Vol. 23, No. 34, September 23, 1994) will comply with the revised policies for format and distribution. The printed edition will include Notices of Availability of Program Announcements (PAs), Requests for Applications (RFAs), and Requests for Proposals (RFPs) and policy notices. The full text of the PAs and RFAs is available online on several platforms as described below, and may be obtained electronically by sending a request via email to NIH program staff identified under the INQUIRIES section of each PA and RFA.

1. Electronic Subscriptions to the NIH Guide

The NIHGDE-L list is open for subscriptions from individuals. To minimize the possibility of errors, it is best for each person to subscribe him/herself to the list. Subscribing and unsubscribing to/from a list is done via e-mail. BITNET users should send mail to LISTSERV@JHUVH, and Internet users to LISTSERV@JHUVH.HCF.JHU.EDU. To subscribe to the E-Guide list, the text of the mail should be:

SUBSCRIBE NIHGDE-L First-name Last-name

The First & Last names should be in upper & lower case; e.g.:

SUBSCRIBE NIHGDE-L Bill Jones

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UNSUBSCRIBE NIHGDE-L

2. Table of Contents

Some users who subscribed to the NIHGDE-L list had problems with the volume of mail that was received each week. They would prefer to see a table of contents, and access the NIH Guide files via Gopher when necessary. For that purpose, the NIHTOC-L list has been established at the NIH. It will contain only the table of contents for each week's NIH Guide. It is an open list that one can subscribe to by sending mail to LISTSERV@NIHLIST or LISTSERV@LIST.NIH.GOV (Internet). The mail should contain as text:

SUBSCRIBE NIHTOC-L First-name Last-name

If you do subscribe to the NIHTOC-L list and are already subscribed to the NIHGDE-L list, you will probably want to UNSUBSCRIBE from that list.

3. NIH Grant Line Bulletin Board

The NIH Grant Line includes information about NIH extramural programs, including the NIH Guide for Grants and Contracts.

A new feature on the NIH Grant Line allows the rapid transmission of files via Bitnet or Internet to a Bitnet or Internet address instead of downloading via a modem.

To access the NIH Grant Line, the terminal emulator must be configured as follows: 1200 or 2400 baud, even parity, 7 data bits, 1 stop bit, half duplex. Using the procedure specified in the communication software, dial 1-301-402-2221. When a response indicates that a connection has been made, type ,GEN1 (the comma is mandatory) and press ENTER; the NIH system will prompt for INITIALS?. Type BB5 and press ENTER. A prompt will ask for ACCOUNT? Type CCS2 and press ENTER.

Messages and a menu will be displayed that allow one to read Bulletins and download Files. Back issues of the NIH Guide are found in different Directories. GUIDE90 has issues going back to July 6, 1990; GUIDE91, GUIDE92, and GUIDE93 have all issues for each year. Type F (for FILES) to access any of the files that are arranged into directories. To get an overview of the kinds of information available, type D (for Directory).

Access to NIH Grant Line via the Internet

To access the NIH Grant Line in an interactive Internet session, Telnet to WYLBUR.CU.NIH.GOV and, when a message has been received that the connection is open, type VT100. At the INITIALS? prompt, type BB5 and at the ACCOUNT? prompt, type CCS2. This puts the user into the NIH Grant Line.

4. NIH Gopher

The NIH Gopher contains information about the NIH, including the NIH Guide for Grants and Contracts, and has text searching capability. One can tunnel to the NIH Gopher at gopher.nih.gov, if one has access to a system with a Gopher client. Local computer support staff should be consulted for additional information.

INQUIRIES

Myra Brockett, Program Analyst
Institutional Affairs Office
National Institutes of Health
Telephone: (301) 496-5366
email: q2c@cu.nih.gov

THE HUMAN BRAIN PROJECT: PHASE I FEASIBILITY STUDIES

NIH GUIDE, Volume 23, Number 33, September 16, 1994

PA NUMBER: PA-93-068

P.T. 34; K.W. 0705010, 1002030, 1004017

National Institute of Mental Health
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National Institute on Alcohol Abuse and Alcoholism
National Science Foundation
Office of Naval Research
National Aeronautics and Space Administration
Department of Energy

For those intending to apply for grants under the Human Brain Project, this addendum is meant to supplement the program announcement PA-93-068; NIH Guide, Vol. 22, No. 13, April 2, 1993, which is still in effect and must be consulted in conjunction with this addendum.

The Human Brain Project is a broadly based Federal research initiative, supported in a coordinated fashion by 14 Federal organizations across five Federal agencies. The general purpose of this initiative is to encourage and support investigator-initiated, basic and clinical neuroscience and behavioral research and development of computer-based resources that could be used to facilitate research on the brain and its functions. Particular emphasis is placed on research and development of tools and approaches to store and manipulate information about the brain and behavior, as well as electronic network technologies which will give scientists access to the stored information and the ability to integrate and synthesize information. The network tools will also provide electronic channels of communication and collaboration to geographically distant laboratories. These capabilities and approaches are referred to here as informatics and include areas such as computer science, mathematics, statistics, and engineering. The combination of brain and behavioral research with informatics research constitutes the developing field of neuroinformatics.

To optimize their utility to brain and behavioral researchers, these technologies and approaches will be developed in the context of specific, ongoing, research on the brain and its functions. Thus, all applications need to have an informatics science research component as well as a research component related to the brain and/or behavior. It is, therefore, expected that each application will include a multidisciplinary research team.

Application components related to ethical, legal, and social issues pertinent to this initiative are encouraged. Also encouraged are components of applications that are designed to reach out to the public, academic, and/or commercial sectors and educate them about the opportunities that are presented by research and development of neuroinformatics.

Participation in an Annual Spring Meeting held in the Washington, DC area is encouraged. In applications for the R01 mechanism, funds to support travel to this meeting should be included in the budget for the principal investigator and up to one additional key member of the research team. In applications for the P20 mechanism, funds to support travel to this meeting should be included in the budget for the principal investigator (the director of the grant), the director of each subproject, and up to one additional key member from the P20 research team.

All applications for these feasibility research grants should include a detailed, year-by-year timetable of specific goals. Applications should:

- o Contain both a brain and/or behavioral research component AND an informatics research component that are well integrated and which promise to move both fields forward
- o Include a specific plan to monitor progress and evaluate tools and approaches being developed

Dates for the submission and resubmission of Phase I Human Brain Project applications and review cycles are as follows:

Letter of Intent Receipt Date:	July 1
Application Receipt Date:	October 15
Administrative Review:	October
Scientific Review:	February/March
Advisory Council Review:	May/June
Earliest Start Date:	July

It should be noted that there is no additional receipt date for resubmitted applications or for competitive continuations (i.e., renewals). All applications, initial submissions, resubmissions, and competitive continuations will be received only once a year, October 15.

Applicants may apply for Interactive Research Project Grants (IRPGs) in addition to the R01 and P20 mechanisms. The IRPG allows for formal interactions between and among research efforts that are funded independently. The IRPG encourages collaborative relationships that do not require extensive, shared, physical resources. A minimum of two independent investigators may submit concurrent, collaborative, cross-referenced individual R01/R29 applications. The proposed projects must not be dependent on each other to the extent that one could not be accomplished in the absence of the other. Applications may be from one or more institutions. Applications will be reviewed independently for scientific merit. Applications judged to have significant and substantial scientific merit will be considered for funding both as independent awards and in the context of the proposed IRPG collaboration. Those interested in applying for an IRPG should consult Program Announcement PA-94-086, NIH Guide, Vol. 23, Number 28, July 29, 1994.

Grantees will be encouraged to take steps to perfect copyright protection of software produced as a result of Human Brain Project funding. These should include prominent notification in the software and its documentation that the software is copyrighted. Notification could consist of the following: "© Copyright [year] by [your name, the names of you and your colleagues, or the name of your institution] with funding from the Human Brain Project."

This notification will identify the source of the software and help ensure that the software can be shared freely while protecting any commercial rights in it. In addition, grantees will be required to agree that they will provide the primary funding organization, upon its request and at a reasonable cost, a copy of any software produced under Human Brain Project funding, with the understanding that the Federal organizations directly involved with the Human Brain Project will have the right to use such software for internal research and archival purposes only and will not permit its distribution beyond those organizations.

INQUIRIES

Women, minorities, and those with disabilities are especially encouraged to apply. Potential applicants are strongly encouraged to contact the Agency or Institute representative to discuss their plans prior to preparing an application. The names of the representatives from each of the participating Agencies, Institutes, and Center may be obtained from:

Michael F. Huerta, Ph.D.
National Institute of Mental Health
5600 Fishers Lane, Room 11-103
Rockville, MD 20857
Telephone: (301) 443-5625
FAX: (301) 443-1731
E-mail (internet): HMI@CU.NIH.GOV

STUDIES TO EVALUATE THE TOXIC AND CARCINOGENIC POTENTIAL OF SELECTED CHEMICALS IN LABORATORY ANIMALS VIA INHALATION

NIH GUIDE, Volume 23, Number 33, September 16, 1994

RFP AVAILABLE: NIH-ES-94-46

P.T.

National Institute of Environmental Health Sciences

The purpose of this contract is to evaluate the toxic and carcinogenic potential of selected chemicals of interest. Exposure to these test chemicals is via inhalation. This project includes two year studies of vanadium pentoxide and naphthalene, prechronic and two year studies of propylene glycol mono-t-butyl ether, decalin and tetralin. The base contract award shall include work activities associated with the development of generation and monitoring methods, as well as health and safety concerns along with 14-day studies of decalin, propylene glycol mono-t-butyl ether, and tetralin. The Government may, pending the availability of funds, exercise options for: a 14-day study of vanadium pentoxide; a 54-day study of naphthalene; 90-day studies of decalin, propylene glycol mono-t-butyl ether, and tetralin; two year studies of vanadium pentoxide, naphthalene, decalin, propylene glycol mono-t-butyl ether, and tetralin; and a special 90-day study of vanadium pentoxide. These studies shall be conducted according to the Specifications for the Conduct of Studies to Evaluate the Toxic and Carcinogenic Potential of Chemical, Biological and Physical Agents in Laboratory Animals for the National toxicology Program¹ dated August 1992, with subsequent revisions. Award of one cost-reimbursement, completion type contract with an estimated period of performance for the base contract of approximately eight months on an open competition basis is contemplated as a result of this solicitation. Exercise of all options under this solicitation could result in a multi-year cost reimbursement type contract with a total term of four years five months.

INQUIRIES

Interested organizations should request either a streamlined or full RFP package. If no selection is made, a streamlined version of the RFP will be provided, which includes only the Statement of Work, deliverables and reporting requirements, special requirements and mandatory qualifications (if any), and technical evaluation criteria. After examination of these documents, any organization interested in responding to this RFP must request the entire RFP in writing or by telephone (919) 541-0416 or by telefax request (919) 541-2712. All responsible sources may submit a proposal that will be considered by the Agency. Expected release date of the RFP is September 19, 1994 with proposals due November 3, 1994. Requests must reference RFP No. NIH-ES-94-46 and are to be forwarded to:

Marilyn B. Whaley
Contracts and Procurement Management Branch, OM
National Institute of Environmental Health Sciences
79 T.W. Alexander Drive, 4401 Building
P.O. Box 12874
Research Triangle Park, NC 27709

ENHANCING RECOVERY IN CORONARY HEART DISEASE (ENRICHD) PATIENTS - CLINICAL UNITS

NIH GUIDE, Volume 23, Number 33, September 16, 1994

RFP AVAILABLE: NHLBI-HC-94-28

P.T.

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) is soliciting proposals from organizations/institutions to serve as clinic units in a multicenter trial to determine the effects of psychosocial interventions on morbidity and mortality in coronary heart disease (CHD) patients. The primary objective of this multicenter trial is to evaluate the effects of psychosocial interventions on the cardiac-related morbidity and mortality of MI patients at high psychosocial risk. High psychosocial risk is defined as the presence of depression and/or social isolation. The study design will compare a psychosocial intervention group, in which patients are provided with social support and psychological treatment designed to decrease social isolation and depression, with a health education control and a standard medical care group, using a combined endpoint of CHD death plus reinfarction. Secondary endpoints include health-related quality of life; adherence to medications and health-promoting behaviors; and ischemic events, measured by ambulatory electrocardiogram and exercise tolerance testing. To accomplish its objective, this program proposes to award approximately eight clinical units for patient accession, intervention, and data collection. It is anticipated that a total of 3,000 patients, or approximately 375 patients shall be enrolled per clinical unit. The period of performance is anticipated for six years beginning in August 1995. The Request for Proposal (RFP) NHLBI-HC-94-28 is available and proposals are due November 18, 1994. Offerors other than continental North American institutions will not be considered based on the need for scientifically comparable data.

INQUIRIES

All requests for this solicitation must be submitted in writing; oral requests must be confirmed either in writing or by FAX. Written requests must include three self-addressed mailing labels, cite RFP NHLBI-HC-94-28, and be sent to:

Cheryl A. Jennings
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
7550 Wisconsin Avenue, Room 3C16
Bethesda, MD 20892

SMALL ANIMAL MODELS OF LENTIVIRUS INFECTION FOR EVALUATING HIV THERAPEUTICS

NIH GUIDE, Volume 23, Number 33, September 16, 1994

RFP AVAILABLE: NIH-NIAID-DAIDS-95-17

P.T.

National Institute of Allergy and Infectious Diseases

The Developmental Therapeutics Branch, Basic Research and Development Program, Division of AIDS, NIAID, NIH, has a requirement for the evaluation of antiviral therapies/strategies for HIV-1/AIDS in established small animal models of lentivirus infection. These capabilities will be used by the Division of AIDS, NIAID, in its effort to develop antiviral therapies/strategies for human subjects infected with HIV-1. Evaluation encompasses in vitro and in vivo determinations of efficacy and toxicity, and when needed, limited pharmacokinetics for in vivo studies. Further characterization and modification of the proposed animal model, or development of other models may be required. Therapies to be tested, alone and in combination, include antiviral agents (drugs and biologics), gene-based and other novel strategies. Examples of lentivirus models considered at this time to be appropriate for this RFP include HIV-1 in immunocompromised mice constituted with human cells or tissues and feline immunodeficiency virus in cats; nonhuman primate models are excluded from the competition.

This announcement is for the recompetition of several current animal model contracts. The RFP is now available and proposals will be due by COB on or about November 30, 1994. It is anticipated that two level-of-effort, cost-reimbursement type contracts will be awarded and that the period of performance for each contract will be four years (estimated start date August 1, 1995). The Government reserves the right to make only one award per animal model and to limit the number of awards based on the merit of the technical proposals received. It is estimated that the Contractor will expend 340 percent effort per year in accomplishment of the Government's objectives for this requirement.

INQUIRIES

A short-form version of the RFP will be available, for informational purposes, which includes only the background information, the full Statement of Work, and Evaluation Criteria. There is sufficient information in this document to enable prospective offerors to determine if they have the expertise/capability to meet the Government's requirements. A full-text version will also be available, which includes all the necessary information, business forms, etc., in order to submit a proposal. There are a limited number of full-text versions available. Therefore, request the short-form RFP first, then the full-text version only if you are going to submit a proposal. All requests must be in writing. Specify if you are requesting the short-version or full-text version of the RFP. FAX requests are acceptable, but written requests containing two self-addressed mailing labels are preferred.

Requests for the RFP must be directed to:

Mr. Bruce E. Anderson
Contract Management Branch
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3C07
6003 Executive Boulevard
Bethesda, MD 20892-7610
Telephone: (301) 496-8371
FAX: (301) 402-0972

CLINICAL CENTERS FOR ETIOLOGY OF SARCOIDOSIS: A CASE CONTROL STUDY

NIH GUIDE, Volume 23, Number 33, September 16, 1994

RFP AVAILABLE: NHLBI-HR-94-21

P.T.

National Heart, Lung, and Blood Institute

The overall objective of this program is to support a six year multi-center case-control study on the potential etiologic factors for sarcoidosis. The program will be conducted in three Phases. Phase I (12 Months) will involve protocol development. Phase II (48 Months) will involve recruitment and follow-up. Phase III will involve data analysis and publication preparation. This program will consist of a clinical coordinating center and up to twelve clinical centers. The clinical centers will recruit 840 sarcoidosis patients and 1680 control subjects for study over a four year period. The cases will also be followed to gain information on the natural history of this disease including risk factors for progression of disease. The protocol to be developed during Phase I (12 Months) will include a comprehensive clinical characterization of each participant and determination of markers of immune responsiveness. Each clinical center will: (1) participate in a cooperative effort with other study investigators to develop and pretest data reporting forms; (2) establish and train staff to conduct the study; (3) enroll, interview, and examine 70 patients (age 21 years or older) with sarcoidosis and, enroll, interview and collect a blood specimen from 140 matched control subjects over a four year period; (4) shall have a patient population composition that will enable the investigators to address factors of gender and ethnicity that are hypothesized to play a role in the susceptibility to and expression of sarcoidosis; (5) document the diagnosis of sarcoidosis in recruited cases by standard clinical criteria, including histologic evidence of non-caseating granulomatous inflammation and exclusion of other diseases; (6) perform follow-up assessment on the patients; (7) assess progression of disease and use of medical care resources; (8) collect data and forward the data to the Clinical Coordinating Center; (9) participate in the biological banking system as managed by the Clinical Coordinating Center in collaboration with the NHLBI-supported repository; (10) work with other study investigators in the preparation and writing of reports and manuscripts for publication; (11) interact with the Clinical Coordinating Center to provide data and related information necessary for data analysis, and (12) work with other study investigators in the preparation and writing of reports and manuscripts for publication.

This announcement is for clinical centers only. A separate Request for Proposals (RFP) for the clinical coordinating center will be released in the near future. This is not a request for proposals. It is anticipated that RFP NHLBI-HR-94-21 will be available on or about September 15, 1994, with proposals due on or about November 30, 1994. It is to be noted that award of a contract for this study shall be made only to offerors who are located in the United States of America.

INQUIRIES

Copies of the RFP may be obtained by submitting a written request along with three self-addressed mailing labels to:

Joanne C. Deshler
Contracts Operations Branch
National Heart, Lung, and Blood Institute
Westwood Building, Room 654
5333 Westbard Avenue
Bethesda, MD 20892

IN VITRO TEST SYSTEMS FOR EVALUATING CHEMOTHERAPIES AGAINST HIV

NIH GUIDE, Volume 23, Number 33, September 16, 1994

RFP AVAILABLE: NIH-NIAID-DAIDS-95-19

P.T.

National Institute of Allergy and Infectious Diseases

The Developmental Therapeutics Branch, Basic Research and Development Program, Division of AIDS of the National Institute of Allergy and Infectious Diseases (NIAID), NIH has a requirement for in vitro test systems to evaluate chemotherapies against HIV. The Contractor will be required to do the following with compounds provided by the Government: evaluate potential therapeutic agents in cell-based in vitro assays for anti-HIV efficacy and cytotoxicity; analyze the data generated in antiviral and cytotoxicity assays; and provide an assessment of the experimental data. The RFP contains mandatory qualification criteria that excludes pharmaceutical companies from participating as an offeror or subcontractor. A pharmaceutical company is defined as an organization which sells drugs or other therapeutic agents for profit.

This announcement is a recompetition for two current contracts (Emory University N01-AI-05078 and IIT Research Institute N01-AI-05077). It is anticipated that there will be two awards. The issuance of the RFP will be on or about September 16, 1994 and proposals will be due by COB on or about December 9, 1994. It is anticipated that two level-of-effort type cost-reimbursement contracts will be awarded and that the period of performance for this contract will be five years. The approximate start date of the contract will be on or about July 9, 1995.

INQUIRIES

A short-form version of the RFP will be available, for informational purposes, which includes only the background information, the full Statement of Work, and Evaluation Criteria. There is sufficient information in this document to enable prospective offerors to determine if they have the expertise/capability to meet the Government's requirements. A full-text version will also be available, which includes all the necessary information, business forms, etc., in order to submit a proposal. Request the short-form RFP first, then the full-text version of the RFP. FAX requests are acceptable, but written requests containing two self-addressed mailing labels are preferred.

Requests for the RFP are to be directed to:

Mr. Ross Kelley
Contract Management Branch
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3C07
6003 Executive Boulevard, MSC 7610
Bethesda, MD 20892-7610
Telephone: (301) 402-2234
FAX: (301) 402-0972

This advertisement does not commit the Government to award a contract. No collect calls will be accepted.

MINORITY DISSERTATION RESEARCH GRANTS IN AGING

NIH GUIDE, Volume 23, Number 33, September 16, 1994

RFA AVAILABLE: AG-95-001

P.T. 34, FF

National Institute on Aging

Application Receipt Date: December 9, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

Small grants to support doctoral dissertation research will be available for minority doctoral candidates intending to study problems in aging.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Minority Dissertation Research Grants in Aging, is related to several priority areas applicable to aging. Potential candidates for the grants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY

Individuals eligible to apply are minority students who belong to a particular racial or ethnic group. In awarding these grants the National Institute on Aging (NIA) will give priority to African Americans, Hispanic Americans, Native Americans and Pacific Islanders or other ethnic or racial group members who have been found to be underrepresented in biomedical or behavioral research. The student must intend to conduct dissertation research on aging.

The doctoral candidate must have a dissertation topic approved by the named committee. This information must be verified in a letter of certification from the thesis chairperson and submitted with the grant application (see APPLICATION PROCEDURES).

The applicant institution must be domestic and must administer the grant on behalf of the proposed investigator. The candidate for dissertation research grant support must be a citizen, or noncitizen national, of the United States or have been lawfully admitted for permanent residence. The performance site may be foreign or domestic.

MECHANISM OF SUPPORT

The mechanism of support is the NIH small grant (R03). Grants may be made for up to two years. Grants to support dissertation research will provide no more than \$30,000 in total direct costs, and no more than \$25,000 in direct costs in any one year.

FUNDS AVAILABLE

The NIA anticipates funding approximately 20 grants with a total cost of up to \$600,000.

SPECIAL REQUIREMENTS

The doctoral candidate must be the designated Principal Investigator on the grant. The principal investigator's salary may not exceed \$12,000 per twelve months. For other special requirements, see the RFA.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

APPLICATION PROCEDURES

Applications are to be prepared on the grant application form PHS 398 (rev. 9/91). The application form is available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number (Minority Dissertation Research Grants in Aging, AG-95-001) must be typed on line 2a of the face page of the application form and the YES box must be marked. Applications must be received by December 9, 1994.

The investigator must submit the original and five copies of the completed application and letters of support. The original and three of these copies must be submitted directly to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Two additional copies of the application must be sent to:

Chief, S.R.O.
National Institute on Aging
Gateway Building, Suite 2C212
7201 Wisconsin Avenue, MSC 9205
Bethesda, MD 20892-9205
ATTN: Minority Dissertation

REVIEW CONSIDERATIONS

Dissertation research grants are competitive. Review will be conducted by a special committee convened by the NIA for this purpose.

AWARD CRITERIA

The anticipated date of award is May 1995. Final funding decisions are based on the recommendations of the reviewers, the relevance of the project to NIA priorities, and the availability of funds.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

direct requests for the RFA and inquiries regarding programmatic issues to:

Dr. Robin A. Barr
Office of Extramural Affairs
National Institute on Aging
7201 Wisconsin Avenue, Suite 2C218 MSC 9205
Bethesda, MD 20892-9205
Telephone: (301) 496-9322

Direct inquiries relating to fiscal matters to:

Mr. Joseph Ellis
National Institute on Aging
Gateway Building, Suite 2N212
7201 Wisconsin Avenue MSC 9205
Bethesda, MD 20892-9205
Telephone: (301) 496-1472

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.366. Awards are made under authorization of the Public Health Service Act Title IV, Part A (Public Law 79-410, as amended by Public Law 99-158, 42 DSC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. The requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs," are not applicable to NIA research grant programs.

NIH GUIDE, Volume 23, Number 33, September 16, 1994

RFA AVAILABLE: RR-94-005

P.T. 34; K.W. 0706000, 0745027, 0795003

National Center for Research Resources
The Whitaker Foundation

Application Receipt Date: December 9, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE NIH CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Center for Research Resources (NCRR) and The Whitaker Foundation invite investigator-initiated research project grant applications for the research and development of devices, instruments, and methodologies for the prevention and control of disease and disabling conditions, and the reduction of health care costs and risks. This solicitation is limited to novel, cost-effective bioengineering approaches in the following areas: (1) microsensors, (2) physiological monitoring, and (3) drug delivery systems.

The Whitaker Foundation (Whitaker) is a private, non-profit foundation that encourages and supports biomedical engineering research and training.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Bioengineering for Disease Prevention and Control, is related to the priority area of disease prevention. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, public and private, non-profit and for-profit organizations such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Women and minority investigators are encouraged to apply.

MECHANISM OF SUPPORT

The mechanism of NCRR support for this program will be the individual research project grant (R01) and the total project period may not exceed four years (three years for foreign applicants). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The NCRR and Whitaker plan to make several awards each in Fiscal Year 1995. The earliest possible award date is July 1, 1995.

Because the nature and scope of the research proposed in response to this RFA will vary, it is anticipated that the size of an award will vary also. This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures.

FUNDS AVAILABLE

The NCRR and Whitaker anticipate making a total of six to eight awards for project periods of up to four years and anticipate that each will set-aside \$1 million for the initial funding period. Funding in response to this RFA is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCRR, the award of research grants pursuant to this RFA by NCRR is contingent on the availability of funds appropriated for Fiscal Year 1995.

RESEARCH OBJECTIVES

Background

The recent explosion of new knowledge in both the physical and biological sciences offers unprecedented opportunities to develop devices, sensors, instruments, and novel methods for use in basic research and clinical care. Many of these technologies, if used appropriately, also should reduce health care costs.

The overall goal of this program, jointly announced and sponsored by the NCRR and Whitaker, is to stimulate the development of new or improved technologies that (1) have the potential to prevent or detect disease and/or disabling conditions in the early stages, when often they can be most efficiently and effectively treated; (2) will reduce the length of hospital stay or eliminate the need for in-patient care altogether; (3) will transfer health care procedures from the hospital to the home or an ambulatory environment; and (4) will provide acute and/or rehabilitation therapy based upon the specific physiological or functional need of the patient.

Objectives and Scope

The objective of this program is to stimulate technological research and development of novel, cost effective bioengineering approaches to the prevention, treatment, or rehabilitation of disease or disabling conditions. Applications need to be based on sound scientific, engineering, and medical rationale. There must be a clearly identified target patient population to which the research is addressed. Since work in technological innovation typically involves many disciplines (e.g., physics, chemistry, biology, engineering), applicants should consider using appropriate multidisciplinary teams in many cases.

Research supported under this program is restricted to the following areas:

- o Microsensors. The emphasis is on devices that are non-invasive, minimally invasive, miniature, stable, and durable.
- o Physiological monitoring. The emphasis is on innovative detection and accurate readout. The monitoring must be a cost effective alternative to current practices.
- o Drug delivery systems. The emphasis is on automating the delivery of the accurate amount of medication when needed by the patient.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). These forms are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 240, Bethesda, MD 20892, telephone (301) 594-7248. Applications must be received by December 9, 1994. Any application received after this date will be considered ineligible for this special solicitation and will be returned to the applicant without review. Applicants are requested to submit a brief letter with their application, co-signed by the institutional official, authorizing that the application and summary statement be made available to Whitaker. The absence of this authorization letter will preclude the possibility of funding by Whitaker.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by NCRR. Incomplete applications will be returned to the applicant without further consideration. If NCRR staff find that the application is not responsive to this RFA, it will be returned without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NCRR in accordance with the peer review criteria stated below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to this RFA. Applications judged to be competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the principal investigator and the official signing for the applicant organization will be promptly notified.

The complete review criteria are included in the RFA.

A second level of review will be provided by the National Advisory Research Resources Council (NARRC), whose review may be based on policy considerations as well as scientific merit. Only applications recommended by NARRC may be considered for funding by the NCRR. Grants made by Whitaker need to be approved by its Foundation Governing Committee.

AWARD CRITERIA

The earliest anticipated award date is July 1, 1995.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Richard DuBois, Ph.D.
Biomedical Research Technology Program
National Center for Research Resources
5333 Westbard Avenue, Room 8A-15
Bethesda, MD 20892
Telephone: (301) 594-7934

Peter Katona, Sc.D.
Biomedical Engineering Programs
The Whitaker Foundation
901 15th Street, N.W.
Washington, DC 20005
Telephone: (202) 408-1505

Direct inquiries regarding fiscal matters to:

Mr. Paul Karadbil
Office of Grants and Contracts Management
National Center for Research Resources
5333 Westbard Avenue, Room 849
Bethesda, MD 20892
Telephone: (301) 594-7955

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.371, Biomedical Research Technology. Awards will be made under authorization of the Public Health Service Act, Title III, Part A (Public Law 78-410, as amended, 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MECHANISMS OF POST BONE MARROW TRANSPLANTATION LUNG INJURY

NIH GUIDE, Volume 23, Number 33, September 16, 1994

RFA AVAILABLE: HL-95-002

P.T.

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: December 1, 1994

Application Receipt Date: January 19, 1995

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Heart, Lung, and Blood Institute (NHLBI) invites research grant applications to support research on immunological, cellular, and molecular mechanisms of post bone marrow transplantation lung injury. The primary objectives of this special grant program are to determine the etiology and to understand the cellular and molecular mechanisms involved in the pathogenesis of idiopathic pneumonia syndrome (IPS) that frequently follows bone marrow transplantation.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Mechanisms of Post Bone Marrow Transplantation Lung Injury, is related to the priority areas of immunization and infectious diseases and cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications from minority individuals, women, and new investigators are encouraged.

MECHANISM OF SUPPORT

This program will be awarded using an incremental funding method that is being tested by the NIH. Refer to the special instructions and the application procedures section in the RFA. Funds must be requested in increments of \$50,000 each (direct costs), or applications will be returned. This RFA solicits applications for the National Institutes of Health (NIH) individual research project grant (R01) support mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. It is anticipated that support for this program will begin in August 1995. Up to four years of support may be requested for these R01s.

For this RFA, funds must be requested in \$50,000 direct cost increments and a maximum of four increments (\$200,000 direct costs) per year may be requested. Only limited budget information will be required and any budget adjustments made by the Initial Review Group will be in increments of \$50,000. Instructions for completing the Biographical Sketch have also been modified. In addition, Other Support information and the application Checklist page will be requested by NHLBI staff upon consideration for an award. The APPLICATION PROCEDURES section of the RFA provides specific details of modifications to standard application instructions.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures.

The National Institute of Allergy and Infectious Diseases (NIAID) also has interest in the immunological/inflammatory/infectious aspects of post bone marrow transplant injury. Therefore, applications that are of mutual interest are likely to be given a secondary assignment to the NIAID in accordance with the NIH referral guidelines.

The estimated funds (total costs) available for the first year of support for the entire program is \$1.5 million. It is anticipated that no more than eight awards will be issued under this program. Since a variety of approaches would represent valid responses to this RFA, it is anticipated that there will be a range of costs among individual grants awarded. Although this program is provided for in the financial plans of the NHLBI, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

Funds will be awarded in lump sum direct cost amounts in increments of \$50,000, less any overlap or other necessary administrative adjustments. Indirect costs will be awarded based on the negotiated rate at the time of each award.

RESEARCH OBJECTIVES

Bone marrow transplantation offers potentially curative treatment for a growing number of patients with a variety of diseases. However, in spite of encouraging developments, transplantation-related complications, especially those involving the lung, have limited the success of bone marrow transplantation. Interstitial pneumonitis is a primary or contributing cause of mortality, accounting for more than 40 percent of deaths related to bone marrow transplantation in most large series. Of these pneumonias, approximately half were attributed to non-infectious idiopathic pneumonia syndrome (IPS). It is also possible that undetectable infectious agents are involved. For the purposes of this RFA, the definition of IPS will be that proposed in the NHLBI Workshop Summary: Idiopathic Pneumonia Syndrome after Bone Marrow Transplantation (Am Rev Respir Dis 1993;147:1601-1606).

A better understanding of the immunological, cellular, and molecular basis of pathogenesis of post transplantation lung injury is needed to identify those at risk and eventually treat or prevent this type of lung tissue injury. Examples of specific aspects of research that are encouraged, but not limited to, under this initiative are as follows: cellular and biochemical mechanisms involved in the afferent phase of the cell-mediated immune response; characterization and regulation of the inflammatory cell population involved in IPS; assessment of the capacity of resident lung cells, (for example, macrophages, lymphocytes, epithelial and endothelial cells) to produce cytokines and their role in generating the inflammatory and immune responses associated with IPS; and immunopathologic roles of infectious agents. These might include latent viral gene expression as it relates to dysregulation of cytokine gene expression and alteration of immune recognition and role of Gram negative bacterial products such as lipopolysaccharide and other cell wall constituents.

The overall objective of this initiative is to encourage basic research on the etiology, mechanisms of pathogenesis, and the host determinants that are involved in the initiation and progression of post bone marrow transplantation lung injury. Applications are invited for innovative multidisciplinary approaches to identify the cause(s) of IPS associated with bone marrow transplantation and to delineate cellular and molecular mechanisms involved in its pathogenesis. Applications submitted in response to this RFA should clearly define the rationale, background, and specific aims of the proposed studies, and should provide a succinct description of the methods and procedures to be used.

The ability to make significant progress in understanding the basic mechanisms involved in IPS would be greatly enhanced by adaptation of animal models, especially small laboratory animals. For example, inbred strains might be used to learn about genetic determinants of post bone marrow transplantation lung injury, and models of pneumonitis, including CMV pneumonitis, might be helpful in determining the role of cytokine-mediated lung injury related to IPS.

In addition to animal studies, innovative studies using human cells or tissues that can be obtained incidentally are desirable. Research involving human subjects should be formulated in the context of mechanistic studies and should address specific hypotheses. Large scale clinical studies are beyond the scope of this RFA.

SPECIAL REQUIREMENTS

Applications that propose descriptive studies and do not contain studies directed at uncovering mechanisms of disease or supporting hypotheses related to mechanisms of disease will not be acceptable. This program will not support studies directed at development of animal models alone. Models must be applied to the study of disease mechanisms associated with post bone marrow transplantation lung injury. Applications that focus on molecular biology and molecular immunology of these disorders are of particular interest.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by December 1, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NHLBI staff to estimate the potential review workload and to avoid conflict of interest in the review. NHLBI staff will not provide a response to a letter of intent. This letter is to be sent to Dr. C. James Scheirer, at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications must be received by January 19, 1995. Submit applications on form PHS 398, (rev. 9/91). Application kits containing this form and the necessary instructions are available in most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248. Additional instructions for completing the PHS 398 are provided in the RFA.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the DRG and responsiveness to this RFA by the NHLBI. Incomplete and/or unresponsive applications will be returned without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by a special emphasis panel convened by the Division of Extramural Affairs, NHLBI, solely to review these applications. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA. Applications judged to be competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the Principal Investigator and the official signing for the applicant organization will be notified.

The personnel category will be reviewed for appropriate staffing based on the requested percent effort and any changes requested in future years. The budget request will be reviewed for consistency with the proposed methods and specific aims. The duration of support will be reviewed to determine if it is appropriate to ensure successful completion of the recommended scope of the project.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from the potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Hannah H. Peavy, M.D.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 6A09
Bethesda, MD 20892
Telephone: (301) 594-7425
FAX: (301) 594-7487

Direct inquiries regarding review matters and address the letter of intent to:

C. James Scheirer, Ph.D.
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 557
Bethesda, MD 20892
Telephone: (301) 594-7478
FAX: (301) 594-7407

Direct inquiries regarding fiscal matters to:

Raymond L. Zimmerman
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A17
Bethesda, MD 20892
Telephone: (301) 594-7420
FAX: (301) 594-7492

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.838. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or to review by a Health Systems Agency.

RFA AVAILABLE: CA-94-030

P.T. 34, FC; K.W. 0715035, 0710030

National Cancer Institute

Letter of Intent Receipt Date: October 28, 1994

Application Receipt Date: January 20, 1995

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Cancer Biology Branch, Division of Cancer Biology, Diagnosis, and Centers (DCBDC), National Cancer Institute (NCI) invites new faculty at Historically Black Colleges and Universities (HBCUs) to apply for small research grants to pursue basic science projects that are relevant to the goals of the NCI. The aim of this RFA is to provide new HBCU faculty with an opportunity to establish a research program to which they will commit time both during the academic year and the summer. It is expected that this opportunity will not only increase the research base at HBCUs, but also broaden the educational experience for students and expand mentoring possibilities.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Small Grants for Historically Black Colleges and Universities, is related to the priority area of cancer. Potential applicants may obtain a copy of "Health People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by Historically Black Colleges and Universities. The faculty member who serves as Principal Investigator (PI) for the project must have had no more than seven years of experience beyond his or her post-doctoral training. Applications from minority and women investigators are especially encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) small grant (R03) mechanism. Applicants will be responsible for the planning, direction, and execution of the proposed projects. The total proposed project period for each application submitted may not exceed three years. The total proposed direct costs for each year may not exceed \$85,000, up to \$35,000 of which may be used for equipment purchases in the first year. The anticipated award date is August 1, 1995.

The award and level of support depends on receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is contingent upon the continuing availability of funds for this purpose. At this time, the NCI has not determined whether this solicitation will be repeated.

FUNDS AVAILABLE

Approximately \$1,000,000 in total costs per year will be committed to fund applications specifically submitted in response to this RFA. It is anticipated that 8 to 10 awards will be made.

RESEARCH OBJECTIVES

This RFA is designed to provide new faculty at HBCUs with an opportunity to initiate cancer-related research projects, sustain their continued professional growth, and build a research base in institutions that often have less than a critical mass of researchers. These specialized small research grants can support pilot projects that have less preliminary data and a narrower scientific focus than is required for an investigator-initiated research project (R01). In addition to the opportunity to implement a research program, this RFA will enable HBCU faculty to involve students in an on-going research project. The ability to observe and participate in on-going cancer research projects at the undergraduate or graduate level would broaden the educational experience for the students, provide mentoring opportunities for the faculty and possibly attract more minority students into scientific and clinical careers in cancer research.

The areas of basic in vitro and in vivo research supported by the NCI, including biology, chemistry, and other disciplines, are appropriate for this RFA; specific examples are cited in the RFA. Collaborations within, or external to, the applicant institution are encouraged whenever they are appropriate to provide resources and expertise that is germane to the research proposed in the application.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by October 28, 1994, a letter of intent that includes a descriptive title of the research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel or collaborators, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NCI staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to Dr. Cheryl L. Marks at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from the NCI program staff listed under INQUIRIES.

Applications must be received by January 20, 1995. If an application is received after that date, it will be returned.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by the NCI. Incomplete applications will be returned to the applicant without further consideration. If NCI staff find that the application is not responsive to the RFA, it will be returned without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NCI in accordance with the review criteria stated below. The second level of review will be provided by the National Cancer Advisory Board.

The review group will assess the scientific merit of the studies according to the following criteria:

1. Scientific and technical feasibility and originality of the proposed research;
2. Appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research;
3. Qualifications of the Principal Investigator and his or her collaborators to perform the research;
4. Availability and adequacy of resources and facilities necessary to perform the research;
5. Appropriateness of the proposed budget in relation to the proposed research;
6. Evidence of commitment by the applicant institution to provide space and appropriate release time from teaching responsibilities to support the proposed research.

INQUIRIES

Written and telephone requests for this RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Dr. Cheryl L. Marks or Dr. Gladys M. Glenn
Division of Cancer Biology, Diagnosis, and Centers
National Cancer Institute
6130 Executive Boulevard, Room 505
Bethesda, MD 20892-7385
Telephone: (301) 496-7028
FAX: (301) 402-1037

Direct inquiries regarding fiscal matters to:

Ms. Michelle Burr
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892-7150
Telephone: (301) 496-7800, Ext. 231
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.396, Cancer Biology Research. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, 42 U.S.C. 214, as amended; Public Law 100-607, 42 U.S.C. 285 and 285a) and administered under PHS grants policies.

NIH GUIDE, Volume 23, Number 33, September 16, 1994

RFA AVAILABLE: AI-94-029

P.T. 34, AA; K.W. 0715008, 0765033

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: November 15, 1994

Application Receipt Date: February 16, 1995

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES" BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of AIDS (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID) invites applications for research designed to study transmission and pathogenesis of HIV-1 in infants and children. Applications are sought for laboratory studies that elucidate: (1) the timing and mechanism of transmission of HIV from mother to infant or (2) factors that determine whether infected children become long-term asymptomatic survivors or suffer from rapidly progressive disease. The NIAID seeks applications for research studies that utilize advances in virology, immunology, and genetics to address these questions. Of special interest are those basic research studies that hold promise for development of clinical strategies to prevent mother-to-infant transmission of HIV-1 or to treat perinatally infected children to prolong and improve the quality of their lives. For applications proposing use of clinical specimens, documented access to an adequate number of samples to address the study hypotheses will be required.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, pediatric AIDS: Factors in Transmission and Pathogenesis, is related to the priority areas of HIV infection, immunization and infectious diseases, and maternal and infant health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-782-3238).

ELIGIBILITY REQUIREMENTS

Research grant applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private institutions, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible to apply for First Independent Research Support and Transition (FIRST) (R29) awards. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The mechanisms of support will be the individual research project grant (R01) and the FIRST (R29) award. Multidisciplinary approaches that involve collaborative efforts among investigators in the fields of basic immunology, molecular biology, genetics, virology, and infectious disease are strongly encouraged. The total project period for an application submitted in response to this RFA may not exceed five years.

This RFA is a one-time solicitation for applications for new and competing renewal awards. Future competing renewal applications will compete with all investigator-initiated applications and will be reviewed according to customary referral and review procedures.

FUNDS AVAILABLE

The estimated total funds (direct and indirect costs) available for the first year of support for all awards made under this RFA will be \$2,000,000. In Fiscal Year 1995, the NIAID plans to fund approximately 12 R01s/R29s. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Applications may not request more than four percent annual inflationary increases for future years. The usual PHS policies governing grants administration and management will apply. Although this program is provided for in the financial plans of the NIAID, awards pursuant to this RFA are contingent upon the availability of funds for this purpose. Funding beyond the first and subsequent years of the grant will be contingent upon satisfactory progress during the preceding years and availability of funds.

RESEARCH OBJECTIVES

Background

Mother to infant transmission of HIV continues to be one of the fastest growing aspects in the worldwide pandemic of AIDS. The World Health Organization has estimated that over 10 million children worldwide will be infected by the year 2000. In the United States, the Centers for Disease Control and Prevention estimate that 10,000 children are currently infected with HIV, and approximately 6000 infants are born annually to HIV-infected women in the U.S. The recent success in the AIDS Clinical Trials Group (ACTG) Protocol 076 suggests that prevention strategies in the perinatal period may be highly efficient at decreasing mother to infant HIV-1 transmission. The ACTG 076 study indicated that women with greater than 200 CD4 cells x 10⁶ /cc³ who initiate treatment with zidovudine (ZDV) during pregnancy can prevent transmission of HIV to their infants in about two-thirds of the cases. However, this study did not address the effectiveness of ZDV in women with less than 200 CD4 counts or who may be infected with ZDV-resistant variants.

Unfortunately, other studies have indicated that women with lower CD4 counts may have an even higher likelihood of transmitting HIV to their infants. The recently initiated trial (ACTG 185) comparing HIV Immune Globulin (HIVIG) with IVIG placebo, both combined with ZDV, will include women with a wider range of CD4 counts and prior anti-retroviral therapy, but results of that trial will not be available for four to five years.

In 1991, the NIAID funded a series of grants focused on two areas of basic research in Pediatric AIDS - early diagnosis of HIV infection and studies to investigate factors involved in mother to infant transmission of HIV. These grants focused primarily on immunological and virological factors influencing mother to infant transmission and have led to many of the concepts about the mode and timing of perinatal HIV transmission. The objectives of this RFA are: to encourage coordinated basic research on the immunology, host genetics, and virology associated with perinatal HIV-1 transmission, its timing and mode, and to identify factors that appear to delay progressive manifestations of pediatric HIV-1 infection.

Scope of Research Sought in This RFA

The NIAID wishes to support continued research in Pediatric AIDS in the following targeted areas.

- o Studies attempting to define the timing of perinatal transmission relative to HIV-1 viral load and disease progression.
- o Coordinated studies of immunological, virological and host genetic factors that might influence perinatal HIV-1 transmission.
- o Studies that evaluate viral pathogenesis with a specific focus on infection of cell subsets in fetuses, neonates and young infants.
- o Studies that investigate oral or mucosal surfaces either as the exposure route for infants or as a source of perinatal infection by AIDS viruses.
- o Studies that evaluate the immunology, physiology, genetics and virology of children with long-term survival of HIV infection.

These are examples of appropriate studies; other studies addressing risk for or timing of transmission of HIV-1 from mother to infant, or disease progression in the infant may be proposed.

Clinical samples, if required, may be drawn from clinical trials or ongoing natural history studies. This solicitation is not intended for direct conduct of clinical trials, patient care, or maintenance of natural history cohorts. Availability of adequate numbers of clinical samples or animal resources to address the study hypotheses MUST BE documented in the application.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details. Copies of these Guidelines may be obtained from program listed under INQUIRIES.

LETTER OF INTENT

Prospective applicants are asked to submit, by November 15, 1994, a letter of intent that includes a descriptive title of the overall proposed research, the name, address and telephone number of the Principal Investigator, and the number and title of this RFA. Although the letter of intent is not required, is not binding, does not commit the sender to submit an application, and does not enter into the review of subsequent applications, the information that it contains allows NIAID staff to estimate the potential review workload and to avoid conflict of interest in the review. The letter of intent is to be sent to Dr. Dianne Tingley at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted on the standard research grant application form PHS 398 (rev. 9/91). Application forms may be obtained from the institution's office for sponsored research or its equivalent and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. Applications must be received by February 16, 1995.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. For purposes of identification and processing, item 2a on the face page of the application must be marked "YES" and the RFA number and the words "PEDIATRIC AIDS: FACTORS IN TRANSMISSION & PATHOGENESIS" must be typed in.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the Division of Research Grants (DRG) and for responsiveness to the RFA by NIAID staff. Incomplete applications will be returned to the applicant without further consideration. If NIAID staff find that the application is not responsive to the RFA, it will be returned without further consideration.

Applications that are complete and responsive to this RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAID. As part of the initial merit review, a process (triage) may be used by the initial review group in which the applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to this RFA. Applications judged to be competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the principal investigator/program director and the official signing for the applicant organization will be promptly notified

AWARD CRITERIA

Funding decisions will be made on the basis of scientific and technical merit as determined by peer review, program priorities, and the availability of funds.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Requests for the RFA and the NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research, as well as inquiries regarding programmatic issues, may be directed to:

Bonnie J. Mathieson, Ph.D. or Patricia E. Fast, M.D., Ph.D.

Division of AIDS

National Institute of Allergy and Infectious Diseases

6003 Executive Boulevard

Solar Building, Room 2B06

Bethesda, MD 20892

Telephone: (301) 496-8200

FAX: (301) 402-1506 or (301) 480-5703

Direct inquiries regarding review issues, address the letter of intent to, and mail two copies of the application and five sets of appendices to:

Dianne Tingley, Ph.D.

Division of Extramural Activities

National Institute of Allergy and Infectious Diseases

6003 Executive Boulevard

Solar Building, Room 4C16

Bethesda, MD 20892

Telephone: (301) 496-0818

FAX: (301) 402-2638

Direct inquiries regarding fiscal matters to:

Ms. Carol Alderson

Division of Extramural Activities

National Institute of Allergy and Infectious Diseases

6003 Executive Boulevard

Solar Building, Room 4B27

Bethesda, MD 20892

Telephone: (301) 496-7075

FAX: (301) 480-3780

Schedule

Letter of Intent Receipt Date: November 15, 1994

Application Receipt Date: February 16, 1995

Scientific Review Date: June/July 1995

Advisory Council Date: September 1995

Earliest Award Date: September 1995

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.856 Microbiology and Infectious Diseases Research and 93.855 Immunology, Allergy and Transplantation Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

SPECIALIZED PROGRAMS OF RESEARCH EXCELLENCE IN PROSTATE CANCER

NIH GUIDE, Volume 23, Number 33, September 16, 1994

RFA AVAILABLE: CA-94-031

P.T.

National Cancer Institute

Letter of Intent Receipt Date: November 18, 1994

Application Receipt Date: February 21, 1995

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Organ Systems Coordinating Branch of the Division of Cancer Biology, Diagnosis and Centers (DCBDC) at the National Cancer Institute (NCI) invites grant applications for Specialized Programs of Research Excellence (SPORE) in Prostate Cancer. The intent of this initiative is to expand the Prostate Cancer SPORes from the current two SPORes to a minimum of three SPORes through open recompetition by making awards to those institutions that are judged to be able to conduct the highest quality balanced translational research approaches on the prevention, etiology, screening, diagnosis, and treatment of prostate cancer. Because basic research in prostate cancer has lagged behind that of the other major solid tumors, greater leeway is given for basic research studies on prostate cancer. However, such studies must have translational potential or significance. SPORes are at institutions that have made or will make a strong institutional commitment to the organization and conduct of these programs. SPORE applicants will be judged on their current and potential ability to translate basic research findings into innovative research settings involving patients and populations. Each SPORE is encouraged to conduct rehabilitation and quality-of-life research. Each SPORE must provide career development opportunities for new and established investigators who wish to pursue active research careers in translational prostate cancer research; develop and maintain human prostate cancer tissue resources that will benefit translational research; develop extended collaborations in critical areas of research need with laboratory scientists and clinical scientists within the institution and in other institutions; and participate with other SPORes on a regular basis to share positive and negative information, assess scientific progress in the field, identify new research opportunities, and promote inter-SPORE collaborations to resolve areas of scientific controversy. Each SPORE and the "network" of SPORes is expected to conduct research that will have the most immediate impact possible on reducing the incidence of and the mortality due to human prostate cancer.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Specialized Program of Research Excellence (SPORE) in Prostate Cancer, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. To be eligible, applicant organizations must have (1) a minimum of three independent investigators who are successful in obtaining peer-reviewed research support directly related to prostate cancer, and who together represent experience in both laboratory and clinical research, or alternatively, a minimum of three independent investigators, each having published articles in peer-reviewed research journals that significantly address prostate cancer, and who as a group represent experience in both laboratory and clinical research; (2) access to a patient care and service facility that serves prostate cancer patients and, if the facility is not part of the parent institution, a statement that assures access to prostate cancer patients for clinical research; the statement must be signed by the responsible officials of the applicant institution and the consortial care facility; (3) while applications must be submitted from a single institution, they may include subcontracted collaborative scientific arrangements with scientists from other institutions as long as these arrangements are clearly delineated, and formally and officially confirmed by signed statements from the responsible officials of each institution. However, a full institutional commitment must come from the parent institution receiving the award.

MECHANISM OF SUPPORT

Support of this program will be through the P50 Specialized Center Grant mechanism. Applicants will be responsible for the planning, direction, and execution of the proposed SPORE program. Except as otherwise noted in this RFA, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement. This RFA is a one-time solicitation. The total project period for a competing P50 renewal SPORE application may not exceed five years; new applicants or applicants that have received P20 SPORE feasibility awards in the past may request up to three years of support. Each new or competing renewal P50 SPORE application may request a maximum annual direct cost of \$1.5 million and maximum annual total cost of \$2.5 million. The earliest anticipated award date is December 1, 1995.

FUNDS AVAILABLE

The NCI anticipates making at least three awards and anticipates setting aside \$2.5 million per award or \$7.5 million total for the initial year's funding. Funding in response to this RFA is dependent upon the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of NCI, the award of grants pursuant to this RFA is contingent upon the anticipated availability of funds for this purpose.

RESEARCH OBJECTIVES

The goal of this RFA is to expand the current Prostate Cancer SPORE program with the addition of at least one new SPORE. Each SPORE assembles critical masses of laboratory and clinical scientists to work together on human prostate cancer and to focus on innovative translation of basic findings into research settings involving patients and populations. The ultimate objective is to reduce incidence and mortality, and to increase and improve survival to the disease. The essential characteristics of a SPORE include (1) a strong scientific program which will have a clear impact on the human disease, (2) a strong innovative developmental or pilot research program which can respond quickly to new research opportunities, (3) a strong career development program to develop and expand the scientific cadre of investigators dedicated to translational research on human prostate cancer, (4) a human prostate cancer tissue procurement resource, an animal model resource, and other resources specifically dedicated to translational research objectives, and (5) a willingness and commitment to work with other SPOREs and scientists in order to maximize research progress.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit by November 18, 1994, a letter of intent that includes the name and address of the principal investigator and identifies the component research projects, core units and their principal investigators, any collaborating institutions, and the number and title of the RFA in response to which the application is being submitted. Although a letter of intent is not required, is not binding and does not enter into the review of subsequent applications, the information that it contains allows NCI staff to estimate the potential review workload and to avoid conflict of interest in the review. Furthermore, NCI staff can discuss the most recent policies of the NCI relative to funding issues, potential problems in meeting eligibility requirements or clarification of the peer review process before the final application is submitted.

The letter of intent is to be sent to Dr. Andrew Chiarodo at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Complete applications are due no later than February 21, 1995. Applications received after this date will not be accepted. The regular research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone: (301) 594-7248; and from the NCI Program Director listed under INQUIRIES.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed initially by the Division of Research Grants for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to this RFA is an NCI program staff function. Applications judged to be non-responsive will be returned without review. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit and for special SPORE characteristics and requirements as described in the complete RFA. Questions concerning the responsiveness of proposed programs to the RFA may be directed to program staff listed under INQUIRIES.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues to, and address the letter of intent to:

Andrew Chiarodo, Ph.D.
Division of Cancer Biology, Diagnosis, and Centers
National Cancer Institute
Executive Plaza North, Suite 512
6130 Executive Boulevard MSC 7386
Bethesda, MD 20852-7386
Telephone: (301) 496-8528

Direct inquiries regarding fiscal matters to:

Joan Metcalfe
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
6120 Executive Boulevard MSC 7150
Bethesda, MD 20892-7150
Telephone: (301) 496-7800 ext. 228

AUTHORITY AND REGULATIONS

This program is described in the catalog of Federal Domestic Assistance no. 13.397. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410 as amended: 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NIH GUIDE, Volume 23, Number 33, September 16, 1994

RFA AVAILABLE: HL-95-001

P.T.

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: December 16, 1994

Application Receipt Date: April 21, 1995

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Heart and Vascular Diseases invites applications to conduct research into the relationship between genes and nutrients in the etiology and prevention of Congenital Cardiovascular Malformations (CCVM). One goal is to foster basic research into the effects of nutrients on embryologic and fetal development of the cardiovascular system. Approaches may include cell and organ culture, the generation of genetically altered animal models and the use of molecular biology and molecular genetics to elucidate the mechanisms underlying those effects. A second goal is to encourage small epidemiologic investigations into the role of nutrients in the pathogenesis of human CCVM.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. This RFA, Gene-Nutrient Interactions in the Pathogenesis of Congenital Heart Defects, is related to the priority areas of maternal and infant health, infant mortality and nutrition. Potential applicants may obtain a copy of 'Healthy People 2000' (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged. Awards in connection with this RFA will be made to foreign institutions only for research of very unusual merit, need and promise and in accordance with PHS policy governing such awards.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA may not exceed five years. The anticipated award date is September 1995. Because the nature and scope of the research may vary, it is anticipated that the size of an award may vary also. This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures.

FUNDS AVAILABLE

The total funds available for the first year of this program (direct plus indirect costs) are \$2,000,000. Funding is expected to begin in September 1995. It is anticipated that no more than eight grants will be awarded under this program.

RESEARCH OBJECTIVES

Two general areas of research are appropriate for this RFA, namely molecular/genetic studies of cardiovascular morphogenesis in animal models and small epidemiologic investigations of the role of nutrients in the pathogenesis of human CCVM. It is anticipated that both approaches will yield much needed information on measures that eventually may prevent some cases of CCVM in humans. Successful applications will have hypotheses to direct the course of the research.

The molecular/genetic research will test hypotheses regarding potential mechanisms by which a nutritional deficiency or toxicity may produce malformations comparable to human CCVM. Given the existing body of literature on Vitamin A/beta-carotene, studies involving retinoid related genes must address the mechanisms by which decreased RA affects normal morphogenesis of the cardiovascular system. Far less information is available regarding the role of other nutrients in organogenesis. Hence, research on the role of vitamins and trace elements in the pathogenesis of CCVM may be more broadly applied.

The use of well-defined animal models, whether naturally occurring or transgenic, is encouraged. Researchers may propose to study gene-nutrient interactions in 'normal' animals fed a nutrient-deficient diet. Investigators also may wish to propose targeted interventions that may correct the abnormal phenotype of an animal model of inherited CCVM. Research resources, such as Keeshond Beagles, which suffer from conotruncal defects, or Yucatan miniature swine, which have a high frequency of ventricular septal defects, may be considered. Similar investigations in humans would be premature and are not appropriate for this RFA.

Large new epidemiologic studies are not likely to be feasible with the budgets allotted for grants awarded under this

RFA; 'add-on' projects may be proposed, however, to take advantage of existing or planned research programs. Studies which propose to make use of already existing epidemiologic data bases or cohorts with well-defined nutrient intake and pregnancy outcomes are acceptable. However, diagnosis of CCVM in children involved in studies must be performed by a pediatric cardiologist, using appropriate techniques such as echocardiography or angiography to avoid errors due to misdiagnosis.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies. All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the program staff or contact person listed below. Program staff may also provide additional relevant information clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and prevention strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

LETTER OF INTENT

Prospective applicants are asked to submit, by December 16, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the principal investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NHLBI staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Dr. C. James Scheirer
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 548B
Bethesda, MD 20892
Telephone: (301) 594-7478
FAX: (301) 594-7407

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 240, Bethesda, MD 20892, telephone 301/594-7248.

Applications must be received by April 21, 1995.

REVIEW CONSIDERATIONS

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NHLBI in accordance with the review criteria stated below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA. Applications judged to be competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the Principal Investigator and the official signing for the applicant organization will be notified. The second level of review will be provided by the National Heart, Lung, Blood Advisory Council.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA and inquiries regarding programmatic issues to:

Dr. Abby G. Ershow
Lipid Metabolism-Atherogenesis Branch
National Heart, Lung, and Blood Institute
Federal Building, Room 401
7550 Wisconsin Avenue MSC 9050
Bethesda, MD 20892-9050
Telephone: (301)496-1681
FAX: (301)496-9882

Direct inquiries regarding fiscal matters to:

Mr. William Darby
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A11
Bethesda, MD 20892
Telephone: (301) 94-7458
FAX: (301) 594-7492

AUTHORITY AND REGULATIONS

The programs of the Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute, are identified in the Catalog of Federal Domestic Assistance, No. 93.837. Awards will be made under the authority of the PHS Act, Section 301 (42 USC 241) and administered under 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.

SPECIALIZED RESEARCH CENTER PROGRAMS OR CENTER CORE GRANTS TO SUPPORT RESEARCH IN REPRODUCTION

NIH GUIDE, Volume 23, Number 33, September 16, 1994

RFA AVAILABLE: HD-95-003

P.T. 34; K.W. 0413002, 0710030

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: January 2, 1995

Application Receipt Date: May 18, 1995

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Reproductive Sciences Branch (RSB), Center for Population Research (CPR), National Institute of Child Health and Human Development (NICHD), supports research on reproduction which relies on a variety of approaches in biomedical sciences. Among the grant mechanisms used to provide research support, the RSB uses:

1. Specialized Research Centers (P50s), which are integrated groups of research projects and supporting core service facilities. The research activities included in such project grants must comprise, by definition, a multidisciplinary approach to biomedical problems in reproduction. Although these research programs may have more than one theme, focus, or emphasis, all of the projects must be responsive to one or more of the specific areas of reproductive research which constitute the mission of the RSB, CPR, NICHD.

2. Center Core Grants (P30s), which support Center Core facilities designed to enhance a group of existing federally supported research projects within the purview of the RSB, CPR, NICHD. Such Center awards require a critical mass of individual, reproductive-oriented awards whose productivity and quality would be increased by support from central technical facilities.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Specialized Research Center Programs or Center Core Grants to Support Research in Reproduction, is related to the area of family planning. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private. Foreign organizations are not eligible.

MECHANISM OF SUPPORT

This RFA will use the Specialized Research Center Program (P50) and Center Core (P30) grant mechanisms to support research in reproduction. The total project period for an application submitted in response to this RFA is five years. The anticipated award date is April 1, 1996.

New Specialized Research Center Grant (P50) applications may not request more than \$600,000 in direct costs for the first year. New Center Core Grant (P30) applications may not request more than \$500,000 in direct costs for the first year. Renewal applications from existing P30 or P50 centers may not request initial year direct costs exceeding 120 percent of the Council recommended direct costs for the final year of the preceding project period. Unless prior written approval of the NICHD has been obtained, applications with requests exceeding these guidelines will be administratively withdrawn by the NICHD and returned to the applicant. Applications prepared for this competition may not propose multi-institutional consortiums.

Although this solicitation is included in the fiscal plans for FY 1996, support for these center grants is contingent upon the receipt of funds for these purposes by the NICHD. The number of grants to be awarded is also contingent upon a sufficient number of applications receiving high enough levels of merit to be considered for an award. It is expected that up to six awards will be made as a result of this RFA within the expected total costs limit of \$4,100,000 available for the first year. At present, the RSB supports a fixed number of centers with a commitment of five years of support that is competitively renewable for additional five-year periods. Support for three P50 Centers and three P30 Centers ends in FY 1996 and it is anticipated that these Centers will submit renewal applications. Although there are no plans to make additional Center awards at this time, new groups of investigators are invited to compete with the current awardees for the existing six awards.

RESEARCH OBJECTIVES

The ultimate goals of biomedical research in the reproductive sciences are to develop new knowledge leading to clinical applications that will enable men and women to control their fertility with methods that are safe, effective, inexpensive, reversible, and acceptable to various population groups, and to overcome problems of infertility and reproductive disorders. Domestic U.S. Reproductive Sciences centers designated as "Specialized Reproductive Sciences Research Centers" (P50s) and as "Reproductive Sciences Research Centers" (P30s) are awarded funds for the support of comprehensive reproductive research programs of high quality that focus on topics deemed to be of high priority and significance because of their critically important relationship to the mission of the RSB, CPR.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by January 2, 1995, a letter of intent that includes a descriptive title of the proposed research and relevant research projects to be associated with the proposed center; the name, address, and telephone number of the Principal Investigator; the identities of other key personnel and participating institutions; and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NICHD staff to estimate the potential review workload and to avoid possible conflict of interest in the review. The letter of intent is to be sent to Julia Lobotsky at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Center grant applications must be structured in accord with the specific policy and formatting guidelines presented in the RFA and the instructions found in the publications entitled either "P50 Specialized Research Center Grant Guidelines" or "P30 Center Core Grant Guidelines" that are available from the NICHD office listed below. Such guidelines require, for example, certain tabulations in addition to the usual instructions for the grant application form PHS 398 (rev. 09/91) used to prepare these applications. The current policies and requirements that govern the research grant programs of NIH will prevail (CFR Title 42, Part 52 and Title 45, Part 75).

REVIEW CONSIDERATIONS

An administrative review of the application will be performed by NIH staff for conformance to NIH policy and NICHD guidelines, as well as for relevance to the program purview of the RSB. Applications that fail to comply with NIH policy and/or NICHD guidelines will be formally returned to the applicant. Applications will be evaluated by the Population Research Committee, NICHD, in November 1995. The second level review will be made by the National Advisory Child Health and Human Development Council in January 1996. Review procedures and criteria are detailed in the P50 Specialized Research Grant Guidelines and P30 Center Core Grant Guidelines (available from NICHD offices listed below).

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Julia Lobotsky, M.S.
Center for Population Research
National Institute of Child Health and Human Development
Building 6100, Room 8801
Bethesda, MD 20892-7510
Telephone: (301) 496-6515

To obtain copies of the NICHD Policy and Formatting Guidelines for P30 and P50 center grant applications, contact:

Susan Streufert, Ph.D.
Division of Scientific Review
National Institute of Child Health and Human Development
Building 6100, Room 5E01
Bethesda, MD 20892-7510

For information on budget and fiscal matters, contact:

Melinda Nelson
Office of Grants and Contracts
National Institute of Child Health and Human Development
Building 6100, Room 8A17K
Bethesda, MD 20892-7510
Telephone: (301) 496-5481

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.864, Population Research. Awards will be made under the authority of the Public Health Service Act 301 (42 USC 241) and 441 (USC 289d) and administered under PHS Grants Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

RESEARCH ON EFFECTIVENESS OF CHILDREN'S MENTAL HEALTH SERVICES

NIH GUIDE, Volume 23, Number 33, September 16, 1994

PA NUMBER: PA-94-094

P.T. 34, AA; K.W. 0730057, 0403001

National Institute of Mental Health

PURPOSE

This program announcement, based on recommendations set forth in the National Plan for Research on Child and Adolescent Mental Disorders, is intended to encourage investigator-initiated research grant applications for studies of the effectiveness of mental health services that are being provided to children, adolescents, and their families through the Center for Mental Health Services (CMHS) Comprehensive Community Mental Health Services Program initiative.

The purpose of this program announcement is to encourage research applications for studies that assess the impact of services funded under this major CMHS program initiative, yield data that can be used in health care reform efforts, and contribute to the development of more effective mental health service delivery systems for children.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Research on the Effectiveness of Children's Mental Health Services, is related to the priority area of mental health and mental disorders. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY

Applications may be submitted by domestic and foreign, public and private, non-profit and for-profit organizations, including universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards and small grants (R03). Women and minority investigators are encouraged to apply.

MECHANISMS OF SUPPORT

Research support may be requested through applications for regular research project grants (R01), small grants (R03), and FIRST award (R29). Since the R03 and R29 mechanisms have different requirements regarding eligibility, application format, and review criteria, applicants are strongly encouraged to consult with program staff (see INQUIRIES) and obtain specialized announcements. The small grant (R03) is especially suited for initial research by junior investigators and for pilot research prior to large-scale field trials. The Investigator-Initiated Interactive Research Project Grant (IRPG) may be used (see PA-94-086, NIH Guide, Vol. 23, No. 28, July 29, 1994). Because of the recent revisions to the IRPG, applicants who are considering this mechanism are particularly advised to consult with program staff.

An application may request support for up to five years for regular research project grants (R01). A small grant (R03) is limited to two years and may not be renewed. A FIRST award (R29) is for five years and are not renewable. Annual awards will be made, subject to continued availability of funds and progress achieved.

RESEARCH OBJECTIVES

Background

Recent reviews of prevalence studies indicate that approximately 14 to 20 percent of children and adolescents in the United States have a diagnosable mental, emotional, or behavioral disorder. Because children with serious emotional disturbances frequently manifest problems in many domains, including home, school, and community, they require the intervention of other agencies and systems to provide special education, child welfare, health, substance abuse, vocational, and, often, juvenile justice services. Service-providing agencies often have requirements and eligibility rules that make it difficult for families whose children have mental health needs to obtain requisite services. Consequently, in the past decade, a growing interest has emerged favoring the provision of a comprehensive array of mental health and other services to meet the needs of these youth and their families.

In response to this interest, the Comprehensive Community Mental Health Services Program for Children with Serious Emotional Disturbances was created (as part of the ADAMHA Reorganization Act--P.L. 102-321, Sec.119). This program is administered by the Center for Mental Health Services (CMHS) of the Substance Abuse and Mental Health Services Administration (SAMHSA). Under this authority, grants are provided to States, political subdivisions of States, Indian tribes, or tribal organizations to provide a broad array of comprehensive community-based services for children with serious emotional, behavioral, or mental disorders in order to enable communities to develop local systems of care consisting of mental health, child welfare, education, juvenile justice, and other appropriate agencies.

Funds for the CMHS program are authorized to be spent on services that are underdeveloped or nonexistent in most communities: respite care; day treatment; therapeutic foster care; intensive home-based services; school or clinic-based services; emergency services; and diagnostic and evaluation services. Additionally, each child must have an individualized service plan, developed with the participation of family and, where appropriate, the child. The plan must designate a case manager to assist the child and family by coordinating services among several systems.

To date, 11 sites have been awarded five-year grants by CMHS under the Request for Applications that was announced in the Spring 1993. Up to 10 additional sites may be awarded by September 30, 1994, under a new CMHS Request for Applications. An evaluation plan that will encompass all of the sites is being developed by CMHS.

Through this program announcement, NIMH invites applications for studies of the effectiveness, including cost-effectiveness, of these comprehensive service models.

Research Topic Areas

Listed below are examples of research topic areas. The list is illustrative, not exhaustive; it is expected that additional important research topics may be identified by researchers who respond to this program announcement.

- o Research on the functional, clinical, or service system outcomes of comprehensive services provided to children, adolescents, and their families, including factors that mediate the outcomes of such services
- o Studies of the effectiveness of different levels of service intensity within service programs, for children and adolescents with different diagnoses, functional abilities, and sociodemographic characteristics
- o Research on the effects of different structural relationships among components of the service systems on providers, children, adolescents, families, and organizational functioning
- o Studies of the relative cost-effectiveness of intervention programs and systems of care
- o Studies of the quality of care or appropriate matching of services to level of impairment
- o Research on the organization and delivery of mental health care across different community settings
- o Studies of the effectiveness and cost-effectiveness of integrating interventions or programs provided by other child-serving sectors, such as substance abuse, schools, child welfare, or juvenile justice, with mental health agencies
- o Research on the family context of mental health service delivery for children and adolescents, such as impact of parent training on families and siblings
- o Research on the effectiveness of interventions designed to prevent adverse mental health outcomes in family members and caregivers
- o Research on factors that are barriers to or facilitators of service integration
- o Studies of the impact of co-occurring conditions, such as emotional/behavioral disorders, drug or alcohol abuse, AIDS, or homelessness on service delivery
- o Development of improved methods for measuring and analyzing service integration and, within comprehensive systems, for measuring service intensity and service outcomes
- o Research on the financing of services for children and adolescents, including financial burden, cost of services for specific mental disorders, and adequacy of services for the uninsured or underinsured
- o Studies of the impact of Medicaid regulations on the delivery of mental health services to children, youth, and families

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies. All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, (Volume 23, Number 11).

Investigators may obtain copies from the program staff or contact persons listed below. Program staff may also provide additional relevant information concerning the policy.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applicants are to use the research grant application form PHS 398 (rev. 9/91). The number (PA-94-094) and the title of this program announcement, "Research on Effectiveness of Children's Mental Health Services," must be typed in item number 2a on the face page of the PHS 398 application form. Applicants must also specify the mechanism under which they are applying (e.g., R01, R03, R29).

FIRST (R29) applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

Application kits containing the necessary forms may be obtained from offices of sponsored research at most universities, colleges, medical schools, and other major research facilities and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248.

The signed original and five legible copies of the completed application must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be reviewed for scientific and technical merit by an initial review group (IRG) composed primarily of non-Federal scientific experts following the standard PHS review procedures. Final review is by the appropriate National Advisory Council; review by Council may be based on policy considerations as well as scientific merit. By law, only applications recommended for consideration for funding by the Council may be supported. Summaries of IRG recommendations are sent to applicants as soon as possible following IRG review.

Review Criteria

Criteria to be considered in evaluating applications for scientific/technical merit are:

- o Scientific and technical significance and originality of the proposed research
- o Appropriateness and adequacy of the research approach and methodology proposed to carry out the research
- o Qualifications and research experience of the principal investigators and staff, particularly but not exclusively in the area of the proposed research
- o Availability of resources necessary to the research
- o Appropriateness of the proposed budget and duration in relation to the proposed research
- o Adequacy of the proposed means for protecting against or minimizing adverse effects to human subjects

AWARD CRITERIA

Factors considered in determining which applications will be funded include IRG and Council recommendations, PHS program needs and priorities, and availability of funds.

INQUIRIES

NIMH staff are available for consultation concerning application development in advance of or during the process of preparing an application. Potential applicants may contact NIMH as early as possible for information and assistance in initiating the application process and developing an application.

Direct inquiries regarding programmatic issues to:

Kimberly Hoagwood, Ph.D.
Child and Adolescent Mental Health Services Research Program
National Institute of Mental Health
5600 Fishers Lane, 10C-06
Rockville, MD 20857
Telephone: (301) 443-4233

For further information on grants management issues, applicants may contact:

Diana S. Trunnell
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-08
Rockville, MD 20857
Telephone: (301) 443-3065

This program is described in the Catalog of Federal Domestic Assistance 93.242, Mental Health Research Grants. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. The program is not subject to the intergovernmental review requirements of Executive Order 12372, as implemented through DHHS regulations at 45 CFR Part 100.

DRUG DISCOVERY FOR OPPORTUNISTIC INFECTIONS ASSOCIATED WITH AIDS

NIH GUIDE, Volume 23, Number 33, September 16, 1994

PA NUMBER: PA-94-095

P.T. 34; K.W. 0715008, 0755025

National Institute of Allergy and Infectious Diseases

PURPOSE

The purpose of this Program Announcement (PA) is to solicit new research grant applications aimed at novel approaches to discovery and preclinical development of therapeutic agents active against opportunistic infections in people with AIDS. The research scope will focus on basic and applied studies necessary to propel advances in improved therapies. The intent of this PA is to invite applications for support of investigator-initiated research grants and the Interactive Research Project Grants (IRPG) mechanisms. No clinical trials will be supported.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Drug Discovery for Opportunistic Infections Associated with AIDS is related to the priority area of human immunodeficiency virus /AIDS. Potential Applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00474-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications may be submitted from one institution or may include arrangements with several institutions, if appropriate. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Applications from or involving minority institutions, individuals, and women are encouraged.

MECHANISM OF SUPPORT

Support for this PA will be by the investigator-initiated research project grant (R01), FIRST (R29) award, or the Interactive Research Project Grants (IRPG) mechanisms. If an IRPG is proposed, it must consist of a minimum of two independent applications (see PA-94-086, NIH Guide for Grants & Contracts, Volume 23, Number 28, July 29, 1994). An IRPG may consist of a combination of R01s and R29s or R01s only, but may not consist solely of R29 applications. An IRPG may also contain shared interactive resources (Cores), which must serve at least two of the research projects in order to facilitate achievement of the Group's common research goals. Collaborative arrangements involving more than one institution are especially encouraged, including participation of the pharmaceutical industry where appropriate. Successful applicants in response to this PA will be invited to participate in the National Cooperative Drug Discovery Groups for the Treatment of Opportunistic Infections Associated with AIDS (NCDDG-OI) program and annual meetings. It is anticipated that awards made in response to this program announcement are likely to provide the foundation for subsequent drug discovery research sponsored through the cooperative agreement mechanism.

RESEARCH OBJECTIVES

Background

Although HIV is the primary cause of the progressive immunological deterioration seen in AIDS, the opportunistic infections (OIs) account for the vast majority of all AIDS-related deaths as well as diminishing quality of life. Pathologic consequences associated with OIs in AIDS are retinitis (cytomegalovirus), pulmonary disease (Pneumocystis carinii), encephalitis (Toxoplasma gondii), meningitis (Cryptococcus neoformans), tuberculosis (Mycobacterium tuberculosis), and disseminated nontuberculosis mycobacterial disease (Mycobacterium avium). The management of OIs in AIDS patients is often difficult and complicated due to: (1) simultaneous infections with other OIs; (2) toxicity and adverse side effects of therapeutic agents; (3) long-term drug use leading to patient intolerance or pathogen drug resistance; (4) occurrence of relapses after discontinuation of therapy; and (5) lack of effective therapies for newly emerging OIs.

Objectives and scope

The objective of this PA is to stimulate drug discovery through original and innovative research focused on key metabolic and pathophysiologic features, which will lead to the development of safe, well-tolerated, and effective new therapies for treatment and prophylaxis of AIDS-associated OIs. Applications based on sound scientific rationale encompassing in vitro culture systems and/or animal models to conduct the necessary preclinical studies are encouraged.

The research scope encourages applications for studies on the following pathogens: human cytomegalovirus (CMV),

Mycobacterium tuberculosis, Mycobacterium avium, Pneumocystis carinii, Toxoplasma gondii, and Cryptococcus neoformans. Innovative research focusing on other particularly prevalent or problematic infections associated with AIDS is also encouraged. Areas of research may include, but are not limited to, studies designed to:

- o Develop in vitro (culture) and in vivo (animal model) systems for drug evaluations against one (or more) opportunistic pathogens.
- o Identify and characterize biochemical, metabolic and molecular properties of the infectious organism that may serve as targets for chemotherapy.
- o Discover new therapeutic agents or prophylactic approaches (e.g., chemo-, immuno-, or gene-based therapies) through exploitation of biochemical, metabolic or molecular differences between pathogen and host.
- o Discover new therapeutic agents through identification and evaluation of promising natural products and synthetic chemical compounds, and elucidate their mechanism of action.
- o Elucidate mechanisms of drug resistance and study strategies to overcome such resistance.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies. All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91), the standard application form for research grants. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. Receipt dates for applications for AIDS-related research are January 2, May 1, and September 1. Applications must adhere to the format and requirements specified in the PHS 398 application kit.

FIRST (R29) applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

For independent R01 or R29 applications, each application must be identified by checking YES on line 2a of the PHS 398 face page, citing this program announcement number. If an IRPG is proposed, each application must be identified along with the number of the program announcement and the phrase "Investigator-initiated IRPG". All R01 or R29 applications constituting the proposed IRPG cohort must be submitted in a single package, whether or not the applications arise from the same institutions. For detailed instructions for preparation and submission of IRPG applications, refer to PA-94-086, NIH Guide for Grants and Contracts, Volume 23, Number 28, July 29, 1994.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director or principal investigator could be included with the application.

Patent Coverage

Attention is drawn to the reporting requirements of 35 U.S.C. Parts 200-212 and 37 CFR Part 401 or FAR 55.227-11. Instructions were also published in the NIH Guide for Grants and Contracts, Vol. 19, No. 23, June 22, 1990. Note that non-profit organizations (including universities) and small business firms retain the rights to any patent resulting from Government contracts, grants or cooperative agreements.

It is also noted that a Presidential memorandum of February 18, 1983 extended to all business concerns, regardless of size, the first option to the ownership of rights to inventions as provided in P.L. 96-517. As a result of this memorandum, the relationships among industrial organizations and other participants are simplified, since all Group members can now be full partners in the research and in any inventions resulting therefrom. The specific patenting arrangements among institutions may vary, and could include joint patent ownership, exclusive licensing arrangements, etc. Applicants are encouraged to develop an arrangement that is most suitable for their own particular circumstances.

Federal regulation clause 37 CFR 401 and HHS Inventions regulations at 45 CFR Parts 6 and 8 require that NIH be informed of inventions and licensing occurring under NIH funded research. Invention and licensing reports must be submitted to Extramural Invention Reports Office, Office of Extramural Research, Building 31, Room 5B41, NIH, 9000 Rockville Pike, Bethesda, Maryland 20892.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Upon receipt, applications and supporting material will be examined by the Division of Research Grants for completeness. Incomplete applications will be returned without further consideration.

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed independently for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures.

Review criteria are:

- o Significance and originality of the research and methodological approaches.
- o Feasibility of the research and adequacy of the experimental design.
- o Interactive nature of the program and of the component IRPGs (where applicable).
- o Training, experience, research competence and commitment of the investigator(s).
- o Adequacy of the facilities and resources.
- o Provisions for the protection of human subjects, the humane care of animals, and biosafety conditions.

Following scientific and technical merit review, applications will receive a second level review by the appropriate National Advisory Council(s).

AWARD CRITERIA

Applications will compete for available funds with all other applications found to have significant and substantial merit. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review.
- o If an IRPG is proposed, the interactive nature of the program and of the component IRPGs as determined by peer review.
- o Availability of funds.
- o Program balance among research areas.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Written instructions for the preparation of IRPG applications are available upon written request. This document, "Special Instructions for Preparing Applications for Investigator-Initiated Interactive Research Project Grants," is available from the Office of Grants Information, Division of Research Grants, NIH, 301-594-7248.

Direct inquiries regarding programmatic issues to:

Dr. Barbara Laughon
Division of AIDS
National Institute of Allergy and Infectious Diseases
Solar Building, Room 2C26
6003 Executive Boulevard, MSC 7620
Bethesda, MD 20892-7620
Telephone: (301) 402-2304
FAX: (301) 402-3211
Email: barbara_laughon@nih.gov

Direct inquiries regarding fiscal matters to:

Ms. Pamela Greenwald
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B22
6003 Executive Boulevard, MSC 7610
Bethesda, MD 20892-7610
Telephone: (301) 496-7075
FAX: (301) 480-3780

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No 93.856, Microbiology and Infectious Diseases Research. Grants are awarded under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under the PHS grants policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of the Executive Order 12372 or Health Systems Agency review.

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

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Vol. 23, No. 34
September 23, 1994

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ATTENTION: The new mailing list for the NIH Guide will be activated in September. Until then, the existing mailing list will be maintained. See INTENT TO MODIFY (NIH Guide, Vol. 23, No. 23, June 17, 1994) for additional information.

This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

THE PUBLIC HEALTH SERVICE (PHS) STRONGLY ENCOURAGES ALL GRANT RECIPIENTS TO PROVIDE A SMOKE-FREE WORKPLACE AND PROMOTE THE NON-USE OF ALL TOBACCO PRODUCTS. THIS IS CONSISTENT WITH THE PHS MISSION TO PROTECT AND ADVANCE THE PHYSICAL AND MENTAL HEALTH OF THE AMERICAN PEOPLE.

TRIAGE AND STREAMLINED SUMMARY STATEMENT FORMAT TO BE USED BY THE DIVISION OF RESEARCH GRANTS

NIH GUIDE, Volume 23, Number 34, September 23, 1994

P.T. 34; K.W. 1014006

National Institutes of Health

Beginning with the review of applications submitted for the October 1, 1994, receipt date, all Division of Research Grants standing study sections will triage investigator-initiated research project grant applications (R01s and R29s). Reviewers will designate approximately half of the applications as "noncompetitive" for support. A designation of "noncompetitive" requires unanimous agreement of the study section.

For this purpose, "noncompetitive" means that the application is judged to be in the lower half, qualitatively, of research project grant applications normally reviewed by that study section. Applications determined to be "noncompetitive" will not receive full discussion at the study section meeting, will not receive a priority score, and will not routinely be taken to second level of review by the national advisory councils/boards.

The summary statement for an application determined to be "noncompetitive" will consist of the customary administrative information and the reviewers' critiques, verbatim. The summary statement for an application that receives full discussion and a score will include, in addition to the reviewers' critiques and the administrative information, a "Resume and Summary of Discussion," which synthesizes the study section's discussion of the application.

Subsequent to the study section meeting, all applicants will receive the customary snap-out mailer to advise them of the outcome of the initial review.

INQUIRIES

Office of Grants Information
Division of Research Grants
Westwood Building, Room 449
Bethesda, MD 20892
Telephone: (301) 594-7248

TREATMENT OF ADMINISTRATIVE AND CLERICAL SALARIES UNDER NIH GRANTS AND COOPERATIVE AGREEMENTS AWARDED TO EDUCATIONAL INSTITUTIONS

NIH GUIDE, Volume 23, Number 34, September 23, 1994

P.T. 34; K.W. 1014006

National Institutes of Health

In July 1993, OMB Circular A-21, "Cost Principles for Educational Institutions," Section F.6.b., was revised to define the criteria for charging salaries of administrative and clerical staff to Federally sponsored grants and cooperative agreements. This revision clarified the principle that the salaries of administrative and clerical staff should usually be treated as indirect costs, but that direct charging of these costs may be appropriate where the nature of the work performed under a particular project requires an extensive amount of administrative or clerical support that is significantly greater than the routine level of such services provided by academic departments. The charging of these costs directly would need to meet the general criteria for direct charging in Section D.1. - i.e., "be identified specifically with a particular sponsored project ... relatively easily with a high degree of accuracy," and the special circumstances requiring direct charging of these services would need to be justified to the satisfaction of the awarding agency in the grant or cooperative agreement application.

Some examples of circumstances where direct charging the salaries of administrative or clerical staff may be appropriate are as follows:

- o Large, complex programs, such as General Clinical Research Centers, primate centers, program projects, environmental research centers, engineering research centers, and other grants and contracts that entail assembling and managing teams of investigators from a number of institutions.
- o Projects that involve extensive data accumulation, analysis and entry, surveying, tabulation, cataloging, searching literature, and reporting, such as epidemiological studies, clinical trials, and retrospective clinical records studies.
- o Projects that require making travel and meeting arrangements for large numbers of participants, such as conferences and seminars.
- o Projects where the principal focus is the preparation and production of manuals and large reports, books and monographs (excluding routine progress and technical reports).
- o Projects that are geographically inaccessible to normal departmental administrative services, such as seagoing research vessels, radio astronomy projects, and other research field sites that are remote from the campus.
- o Individual projects requiring significant amounts of project-specific database management; individualized graphics or manuscript preparation; human or animal protocol, IRB preparations and/or other project-specific regulatory protocols; and multiple project-related investigator coordination and communications.

These examples are not exhaustive nor are they intended to imply that charging of administrative or clerical salaries would always be appropriate for the situations illustrated in the examples above. Where direct charges for administrative and clerical salaries are made (as with other administrative type costs, e.g., telephones, postage, books and journals), care must be exercised to assure that costs incurred for the same purpose in like circumstances are consistently treated as direct costs for all activities. This should be accomplished through a "Direct Charge Equivalent" or other mechanism that assigns the costs directly to the appropriate activities.

NIH Implementation

For those institutions subject to OMB Circular A-21, the NIH will implement the revision effective with budget period start dates on or after October 1, 1994, for competing grants and cooperative agreements. For noncompeting grants and cooperative agreements, the NIH will not make any adjustments to the committed level, nor will future year commitments be adjusted. Nonetheless, the principles of A-21 address the appropriate allocation of these costs with implementation based on the negotiated indirect cost rate agreement in effect for each institution. Thus, grantee institutions that have negotiated indirect rates based on the revised principles contained in Section F.6.b may not directly charge administrative or clerical salaries when inconsistent with the Circular, even though these costs may not have been deleted from the noncompeting award.

This revision also affects any postaward rebudgeting of funds for the purpose of charging administrative or clerical salaries. Where grant or cooperative agreement applications do not anticipate the need to directly charge administrative and clerical salaries, institutions may rebudget funds, without awarding office prior approval, to cover these costs when consistent with the criteria and examples described above. For example, administrative or clerical salaries not identified in the application could be charged to the Training Related Expenses associated with Institutional National Research Service Awards (T32) when the activity involves a large amount of tracking and completion of forms directly related to the purpose of the grant.

The implementation of this revision will not have any impact on the peer review of grant applications. Reviewers will continue to base any recommended budget reduction on whether the cost requested is warranted or justified for the project. Reviewers should not recommend deletion of requested administrative and clerical staff salary support based solely on the provisions contained in Circular A-21. The awarding unit staff will determine, in accordance with A-21, whether or not the costs are allocable as a direct cost under the particular project.

INQUIRIES

Questions should be addressed to the awarding agency's Grants Management Officer when it is unclear whether or not administrative or clerical staff salaries may be charged directly.

NIH SOUTHWEST REGIONAL SEMINAR IN PROGRAM FUNDING AND GRANTS ADMINISTRATION

NIH GUIDE, Volume 23, Number 34, September 23, 1994

P.T. 34; K.W. 1014006

National Institutes of Health

A regional seminar covering topics related to program funding and grants administration at the National Institutes of Health has been scheduled for November 17-18, 1994, in Albuquerque, New Mexico. The seminar, hosted by the Offices of Research Administration and Continuing Medical Education at the University of New Mexico, is intended to attract faculty and research administrators from the southwest region of the United States, although those interested from other regions are also invited and welcome. Staff from small and minority colleges, for-profit research organizations, hospitals, universities, and medical centers are encouraged to attend.

This two-day seminar will have a dual focus of interest to both academic researchers and new and senior research administrators. Discussions of current issues that affect NIH funding and grants administration will be featured to give seminar participants a comprehensive view of NIH-sponsored research. There will be time available to network with colleagues and meet informally with NIH representatives to discuss topics of special interest.

The faculty will include Geoffrey Grant, Joellen Harper, and Sue Ohata from the Office of Policy for Extramural Research Administration; Wayne Berry, Division of Financial Management; Faye Calhoun, Ph.D., Division of Research Grants; Joseph Ellis, NIA; Marvin Kalt, Ph.D., NCI; Mary Kirker, NIAID; Yvonne Maddox, Ph.D., NIGMS; and Carol Tippery, NIGMS.

SEMINAR LOGISTICS

Seminar Leader:

Geoffrey Grant, Acting Director
Office of Policy for Extramural Research Administration (OPERA)

Seminar Coordinator (NIH):

Joellen Harper, Grants Policy Office, OPERA, 301/496-5967

Seminar Coordinator (University of New Mexico):

Dorrie Murray, Office of Continuing Medical Education, University of New Mexico, 505/277-3942

Dates: Thursday and Friday, November 17-18, 1994

Location

Ramada Hotel Classic
6815 Menaul N.E.
Albuquerque, NM 87110
Telephone: (505) 881-0000 or 800/252-7772

Participants need to make hotel reservations directly and should reference the regional seminar when you call. Reservations made by October 16, 1994, are guaranteed the special room rate of \$68 (single) or \$78 (double).

Cost: \$125 early-bird registration (\$150 after November 3)

Registration and Inquiries:

Advance registration is required. You are encouraged to register early, as space is limited. To receive the draft program and registration materials, call 505/277-3942, or send a fax that provides your name, institution, address, telephone number, and anticipated number of registrants to 505/277-8604.

FUTURE SEMINARS

At this time, the dates and locations for regional seminars to be held in 1995 and beyond have not yet been finalized. If you have any questions about hosting a regional seminar, contact Ms. Joellen Harper in the NIH Grants Policy Office on 301/496-5967.

NATIONAL ANIMAL WELFARE EDUCATION WORKSHOP

NIH GUIDE, Volume 23, Number 34, September 23, 1994

P.T. 34; K.W. 0201011, 1014003

National Institutes of Health

The National Institutes of Health (NIH), Office of Extramural Research (OER), Office for Protection from Research Risks (OPRR) is cosponsoring a National Animal Welfare Education Workshop with The Louisiana State University Medical Center and Xavier University of Louisiana on September 29-30, 1994. The topic is Use of Animals in Research and Alternatives. The day and a half program will be held at The Monteleone Hotel, 214 Royal Street, New Orleans, LA, telephone (504) 523-3341 or 1-800-535-9595.

The day and a half program will address various aspects of the use of animals in research and the role of animals and alternatives in research and education. The workshop will address such issues as: Adequacy of Computer Searches: OPRR, USDA, AAALAC, FDA Perspectives on Alternatives: Occupational Health Program: Implementation, Update and Biosafety Concerns: Role of Animals and Alternatives in Education: NIH Plan for Use of Animals in Research: Fostering the three Rs and other relevant topics.

The Workshop is open to all persons involved in the management and/or oversight of an institutional animal care and use program including institutional administrators, members of Institution Animal Care and Use Committees, laboratory animal veterinarians, investigators, and technicians.

The registration fee is \$150.00.

INQUIRIES

For information concerning registration, contact:

Mrs. Lois Herbez
Division of Animal Care, LSU Medical School
1542 Tulane Avenue
New Orleans, LA 70112-2822
Telephone: (504) 568-4198
FAX: (504) 568-4843

For further information concerning future NIH/OPRR Animal Welfare Education Workshops, contact:

Mrs. Roberta Sonneborn
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 5B63
Bethesda, MD 20892
Telephone: (301) 496-7163
FAX: (301) 402-2803

SPEECH PROCESSORS FOR AUDITORY PROTHESES

NIH GUIDE, Volume 23, Number 34, September 23, 1994

RFP AVAILABLE: NIH-DC-94-25

P.T. 34; K.W. 0740030, 0740060

National Institutes of Health

The National Institute on Deafness and Other Communication Disorders, National Institutes of Health, has a requirement to design, develop, and evaluate laboratory-based speech processor emulators and wearable speech processors for auditory prostheses. In addition, a need exists for new auditory testing material to evaluate the advantages and disadvantages of changes in speech processor designs. A three-year term form, cost-reimbursement contract is anticipated. The solicitation is scheduled to be issued on or about September 30, 1994. Proposals will be due 60 days after the date of issuance of the solicitation. All responsible sources may submit a proposal that will be considered by the Government.

INQUIRIES

Copies of the solicitation may be obtained by sending a written request to:

Barbara Oxenham
Division of Grants and Contracts
National Institutes of Health
6100 Executive Boulevard, Room 6E01 MSC 7540
Bethesda, MD 20892-7540
Telephone: (301) 496-4487

THE FEASIBILITY OF A COCHLEAR NUCLEUS AUDITORY PROTHESIS BASED ON MICROSTIMULATION

NIH GUIDE, Volume 23, Number 34, September 23, 1994

RFP AVAILABLE: NIH-DC-95-02

P.T. 34; K.W. K.W. 0740030, 0745047

National Institutes of Health

The National Institute on Deafness and Other Communication Disorders, National Institutes of Health, has a requirement to study the feasibility of an auditory prosthesis based on microstimulating electrodes placed into the ventral cochlear nucleus. Although this research will be limited to animal studies, the ultimate goal is an auditory prosthesis for deaf individuals who cannot benefit from a cochlear prosthesis. A three-year term form, cost reimbursement contract is anticipated. The solicitation is scheduled to be issued on or about September 28, 1994. Proposals will be due 60 days after the date of issuance of the solicitation. All responsible sources may submit a proposal that will be considered by the Government.

INQUIRIES

Copies of the solicitation may be obtained by sending a written request to:

Barbara Oxenham
Division of Grants and Contracts
National Institutes of Health
6100 Executive Boulevard, Room 6E01 MSC 7540
Bethesda, MD 20892-7540
Telephone: (301) 496-4487

RESEARCH ON THE BIOLOGY OF THE PULP

NIH GUIDE, Volume 23, Number 34, September 23, 1994

RFA AVAILABLE: DE-94-009

P.T. 34; K.W. 0715148, 1002008, 0710085

National Institute of Dental Research

Letter of Intent Receipt Date: December 15, 1994
Application Receipt Date: January 18, 1995

PURPOSE

The National Institute of Dental Research (NIDR) encourages studies leading to a better understanding of the reactions of the pulp-dentin complex in health and disease and how these tissues are involved in responding to various challenges. A thorough understanding of pulp biology, its normal function and physiology, and its pathology and its interaction with the immune system is decisive for the success of operative dentistry and endodontics. The intent of this Request for Application (RFA) is to stimulate research in both basic and applied disciplines of dentistry by multi-methodological approaches. This aim can be achieved through interactions by researchers in such fields as cell biology,

neurophysiology, operative dentistry, and endodontics, in academia, government and industry.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Research on the Biology of the Pulp, is related to the priority area of oral health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

INQUIRIES

The RFA, which describes the research objectives, applications procedures, review considerations and award criteria for this solicitation, may be obtained electronically through the NIH Grant Line (data line 301/402-2221) and the NIH GOPHER (Internet) and by mail and email from the program contact listed below.

Joyce A. Reese, D.D.S., M.P.H.
Extramural Program
National Institute of Dental Research
Westwood Building, Room 509
Bethesda, MD 20892
Telephone: (301) 594-7648

ENHANCEMENT AWARDS FOR UNDERREPRESENTED MINORITY RESEARCHERS IN HIV/AIDS

NIH GUIDE, Volume 23, Number 34, September 23, 1994

RFA AVAILABLE: AI-94-027

P.T. 34, FF; K.W. 0715008, 0710030

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: December 23, 1994

Application Receipt Date: February 21, 1995

PURPOSE

The goal of this support is to enable underrepresented minority investigators to establish clinical or basic AIDS research programs. To move towards this goal, the National Institute of Allergy and Infectious Disease (NIAID) encourages applications from underrepresented minority investigators for both basic and clinical investigations in AIDS and AIDS-related research. Several features have been employed to achieve these goals. These include the fostering of specific collaborations between more established investigators and the Principal Investigator (PI) to enhance refinement and implementation of each proposed project to maximize the chances for success. Support will also be provided for laboratory staff of the qualified PI, including postdoctoral scientists who will augment the research program established by the grantee. Applications in all basic and clinical areas of HIV/AIDS research are encouraged. The NIAID anticipates awarding four to six R01 awards, for a total (direct and indirect) cost of approximately \$1.2 million for the initial year of funding.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), Enhancement Awards for Underrepresented Minority Researchers in HIV/AIDS, is related to the priority area of HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone (202) 783-3238).

INQUIRIES

The RFA, which describes the research objectives, application procedures, review considerations, and award criteria for this solicitation, may be obtained electronically through the NIH Grant Line (data line 301/402-2221) and the NIH GOPHER (Internet) and by mail and email from the program contact listed below.

Dr. Janet M. Young
Division of AIDS
National Institute of Allergy and Infectious Diseases
Solar Building, Room 2C36
Bethesda, MD 20892
Telephone: (301) 402-0755
FAX: (301) 480-5703
INTERNET: enhance@nih.gov

RESEARCH INFRASTRUCTURE SUPPORT PROGRAM

NIH GUIDE, Volume 23, Number 32, August 26, 1994

PA AVAILABLE: PAR-94-096

P.T. 34; K.W. 0715095, 0730057

National Institute of Mental Health

PURPOSE

The National Institute of Mental Health (NIMH) is seeking to expand the number of institutions capable of supporting state-of-the-art mental health clinical and services research and thus increase the number of investigators in the Nation with the skills needed to conduct research in these areas. The Research Infrastructure Support Program (RISP) is in response to recommendations made by the National Advisory Mental Health Council and by the NIMH Extramural Science Advisory Board.

This program announcement supersedes and replaces NIMH announcement PA-93-003, Research Infrastructure Program (RISP), dated September 1992.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Research Infrastructure Support Program (RISP), is supportive of the priority area of mental health and mental disorders. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

INQUIRIES

The program announcement, which describes the research objectives, applications procedures, review considerations, and award criteria for this program, may be obtained electronically through the NIH Grant Line (date line 301/402-2221) and the NIH GOPHER (Internet) and by mail and email from the program contact listed below.

Thomas L. Lalley, M.A.
Division of Epidemiology and Services Research
National Institute of Mental Health
Room 10C-06 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-3364
Internet: TLALLEY@AOAMH2.SSW.DHHS.GOV

ERRATA

POSTDOCTORAL TRAINING IN ALTERNATIVE MEDICINE

NIH GUIDE, Volume 23, Number 34, September 23, 1994

PA NUMBER: PA-94-025

P.T. 44; K.W. 0720005, 0710030

Office of Alternative Medicine
National Institutes of Health

The following changes are made to PA-94-025, which was published in the NIH Guide for Grants and Contracts, Vol. 23, No 1, January 7, 1994:

Under the section PURPOSE the first sentence should read: "The Office of Alternative Medicine (OAM) solicits applications for individual postdoctoral training awards using the National Research Service Award (NRSA) mechanism".

Under the section MECHANISM OF SUPPORT, delete the last sentence, third paragraph.

INQUIRIES

Direct inquiries regarding programmatic issues to:

Dr. John Spencer
Office of Alternative Medicine
National Institutes of Health
6120 Executive Boulevard, Suite 450
Rockville, MD 20892-9904
Telephone: (301) 402-4333
FAX: (301) 402-4741

NIH GUIDE, Volume 23, Number 34, September 23, 1994

RFA: AI-94-029

P.T. 34, AA; K.W. 0715008, 0765033

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: November 15, 1994

Application Receipt Date: February 16, 1995

The following correction is issued for RFA AI-94-029, which was published in the NIH Guide for Grants and Contracts, Vol. 23, No. 33, September 16, 1994:

REVIEW CONSIDERATIONS

Whenever appropriate, the adherence to NIH guidelines concerning adequate representation of women and minorities in human subjects research will be evaluated and considered in the determination of the priority score.

While the following review factors do not usually influence the priority score, they are nonetheless carefully considered by the initial review group: the appropriateness of the requested budget to the work proposed and the adequacy of protection of human subjects and/or animals in research. Any documented concerns expressed by the initial review group about any of these factors on a given application may influence the recommendation of the Advisory Council concerning funding of that application.

INQUIRIES

Direct inquiries regarding programmatic issues to:

Bonnie J. Mathieson, Ph.D. or Patricia E. Fast, M.D., Ph.D.

Division of AIDS

National Institute of Allergy and Infectious Diseases

Solar Building, Room 2B06

6003 Executive Boulevard

Bethesda, MD 20892

Telephone: (301) 496-8200

FAX: (301) 402-1506 or (301) 480-5703

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

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